TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

(Authority: A.R.S. § 32-1904 et seq.)

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ARTICLE 1. ADMINISTRATION

R4-23-101. General

A. 4 A.A.C. 23 applies to all actions and proceedings of the Board and shall be deemed a part of the record in any Board action or proceeding without formal introduction of, or reference to the rules. A party to a Board action is deemed to have knowledge of the rules. The Board office shall provide a copy of the rules:

1. To each license applicant who submits a completed application packet; and
2. To each permit applicant during the final compliance inspection after the Board approves the permit application.

B. The Board, within its jurisdiction, may, in the interest of justice, excuse the failure of any person to comply with the rules.

C. The Board, within its jurisdiction, may grant an extension of time within which to comply with any rule when it deems the extension to be in the interest of justice.

Historical Note
Former Rules 1.1000, 1.1200, and 1.1300; Amended effective August 23, 1978 (Supp. 78-4).

R4-23-102. Meetings

A. The Board shall hold not less than four meetings per fiscal year to conduct general business and interview permit and license applicants.

B. A special meeting of the Board may be held at any time subject to the call of the President or a majority of the Board members and in compliance with the notification requirements of A.R.S. § 38-431.02.

Historical Note
Former Rules 1.2100, 1.2200, 1.2300, and 1.2400. Amended by final rulemaking at 7 A.A.R. 2143, effective May 1, 2001 (Supp. 01-2).

R4-23-103. Repealed

Historical Note
Former Rules 1.3100, 1.3200, 1.3300, and 1.3400; Amended subsection (C) effective August 9, 1983 (Supp. 83-4).

R4-23-104. Repealed

Historical Note
Former Rules 1.4011, 1.4110, 1.4120, 1.4200, 1.4210, 1.4220, 1.4300, 1.4400, 1.5500, 1.5600, 1.5700, and 1.4500; Amended effective August 23, 1978 (Supp. 78-5); Amended by deleting subsection (B) and renumbering subsections (C) through (J) as subsections (B) through (I) effective August 9, 1983 (Supp. 83-4). Amended effective February 8, 1991 (Supp. 91-1).

R4-23-105. Repealed

Historical Note
Former Rules 1.5100, 1.5200, 1.5300, and 1.5400; Amended subsection (B) effective August 9, 1983 (Supp. 83-4).

R4-23-106. Repealed

Historical Note
Former Rules 1.5800 and 1.5900.

R4-23-107. Repealed

Historical Note
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R4-23-108. Repealed

Historical Note
Former Rule 1.5930.

R4-23-109. Repealed

Historical Note
Former Rules 1.7100, 1.7200, and 1.7300. Amended effective July 14, 1977 (Supp. 77-4). Amended effective February 8, 1991 (Supp. 91-1).

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Active ingredient" means any component that furnishes pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or that affects the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug, that are present in the finished drug product in a modified form, and that furnish the specified activity or effect.

"Alternate physician" means a physician licensed under A.R.S. Title 32 Chapter 13 or 17 who signs a drug therapy management agreement to temporarily assume responsibility for supervision and evaluation of the drug therapy management performed by a pharmacist when the supervisory physician is unavailable by direct telecommunication or physical presence at the practice site.

"Approved course in pharmacy law" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations.

"Approved Provider" means an individual, institution, organization, association, corporation, or agency that is approved by the American Council on Pharmaceutical Education (ACPE) in accordance with ACPE's policy and procedures or by the Board as meeting criteria indicative of the ability to provide quality continuing education.

"Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

"AZPLEX" means an Arizona pharmacy law examination written and administered by the Board staff or a Board-approved national pharmacy law examination written and administered in cooperation with NABP.

"Batch" means a specific quantity of drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

"Beyond-use date" means a date determined by a pharmacist and placed on a prescription label at the time of dispensing to indicate a time beyond which the contents of the prescription are not recommended to be used.

"Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents when there is a need for protection of the product, personnel, and environment, consistent with National Sanitation Foundation (NSF) standards, published in the National Sanitation Foundation Standard 49, Class II (Laminar Flow) Biohazard Cabinetry, NSF International P. O. Box 130140, Ann Arbor, MI, revised June 1987 edition, (and no future amendments or editions),

incorporated by reference and on file with the Board and the office of the Secretary of State.

"Class 100 environment" means an atmospheric environment in compliance with the Federal Standard 209 Clean Room and Work Station Requirements: Controlled Environment, publication FED-STD-209D, U.S. Government Services Administration 450 Golden Gate Avenue, San Francisco, CA, June 15, 1988 edition which includes January 28, 1991, changes, (and no future amendments or editions), incorporated by reference and on file with the office of the Secretary of State.

"Community pharmacy" means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited service pharmacy.

"Component" means any ingredient used in compounding or manufacturing drugs in dosage form, including an ingredient that may not appear in the finished product.

"Compounding and dispensing counter" means a pharmacy counter working area defined in this Section where a pharmacist or a graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist compounds, mixes, combines, counts, pours, or prepares and packages a prescription medication to dispense an individual prescription order or prepackages a drug for future dispensing.

"Computer system" means an automated data-processing system that uses a programmable electronic device to store, retrieve, and process data.

"Computer system audit" means an accounting method, involving multiple single-drug usage reports and audits, used to determine a computer system's ability to store, retrieve, and process original and refill prescription dispensing information.

"Contact hour" means 50 minutes of participation in a continuing education activity sponsored by an Approved Provider.

"Container" means:

A receptacle, as described in the official compendium or the federal act, that is used in manufacturing or compounding a drug or in distributing, supplying, or dispensing the finished dosage form of a drug; or

A metal receptacle designed to contain liquefied or vaporized compressed medical gas and used in manufacturing, transfilling, distributing, supplying, or dispensing a compressed medical gas.

"Continuing education" means a structured learning process required of a licensed pharmacist to maintain licensure that includes study in the general areas of socio-economic and legal aspects of health care; the properties and actions of drugs and dosage forms; etiology, characteristics and therapeutics of disease status; or pharmacy practice.

"Continuing education activity" means continuing education obtained through an institute, seminar, lecture, conference, workshop, mediated instruction, programmed learning course, or postgraduate study in an accredited college or school of pharmacy.

"Continuing education unit" or "CEU" means 10 contact hours of participation in a continuing education activity sponsored by an Approved Provider.

"Correctional facility" has the same meaning as in A.R.S. §§ 13-2501 and 31-341.

"CRT" means a cathode ray tube or other mechanism used to view information produced or stored by a computer system.

"Current good compounding practices" means the minimum standards for methods used in, and facilities or controls used for, compounding a drug to ensure that the drug has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Current good manufacturing practice" means the minimum standard for methods used in, and facilities or controls used for manufacturing, processing, packing, or holding a drug to ensure that the drug meets the requirements of the federal act as to safety, and has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Cytotoxic" means a pharmaceutical that is capable of killing living cells.

"Day" means a calendar day unless otherwise specified.

"DEA" means the Drug Enforcement Administration as defined in A.R.S. § 32-1901.

"Delinquent license" means a pharmacist or intern license the Board suspends for failure to renew or pay all required fees on or before the date the renewal is due.

"Dietary supplement" means a product (other than tobacco) that:

Is intended to supplement the diet that contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients;

Is intended for ingestion in pill, capsule, tablet, or liquid form;

Is not represented for use as a conventional food or as the sole item of a meal or diet; and

Is labeled as a "dietary supplement."

"Dispensing pharmacist" means a pharmacist who, in the process of dispensing a prescription medication after the complete preparation of the prescription medication and before delivery of the prescription medication to a patient or patient's agent, verifies, checks, and initials the prescription medication label, as required in R4-23-402(A).

"Drug sample" means a unit of a prescription drug that a manufacturer provides free of charge to promote the sale of the drug. No person shall sell, purchase, or trade or offer to sell, purchase, or trade a drug sample.

"Drug therapy management" means any act or service provided by a pharmacist in compliance with a Board-approved drug therapy management agreement.

"Drug therapy management agreement" means a written protocol, approved and signed by a supervisory physician, alternate physician, and pharmacist that specifies the conditions under which a pharmacist:

Assesses patient status;

Orders and interprets laboratory tests; and

Modifies, implements, or monitors patient drug therapy.

"Extreme emergency" means the occurrence of a fire, water leak, electrical failure, public disaster, or other catastrophe

constituting an imminent threat of physical harm to pharmacy personnel or patrons.

"FDA" means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for foods, drugs, cosmetics, and other consumer products.

"Immediate notice" means a required notice sent by mail, facsimile, or electronic mail to the Board Office within 24 hours.

"Inactive ingredient" means any component other than an "active ingredient" present in a drug.

"Internal test assessment" means performing quality assurance or other procedures necessary to ensure the integrity of a test.

"Limited-service correctional pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that:

Holds a current Board permit under A.R.S. § 32-1931;

Is located in a correctional facility; and

Uses pharmacists, interns, and support personnel to compound, produce, dispense, and distribute drugs.

"Limited-service long-term care pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board-issued permit and dispenses prescription medication or prescription-only devices to patients in long-term care facilities.

"Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.

"Limited-service nuclear pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and provides radiopharmaceutical services.

"Limited-service pharmacy permittee" means a person who holds a current limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and R4-23-606.

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.

"Long-term care facility" or "LTCF" means a nursing care institution as defined in A.R.S. § 36-401 or an assisted living facility that:

Provides 24-hour, seven-day a week licensed nursing services to resident patients; and

Is licensed by the Arizona Department of Health Services.

"Lot" means a batch or any portion of a batch of a drug, or if a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures its uniformity. In either case, a lot is identified by a distinctive lot number and has uniform character and quality with specified limits.

"Lot number" or "control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the compounding or manufacturing, control, packaging, and distribution of a batch or lot of a drug can be determined.

"Materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

"Mediated instruction" means information transmitted via intermediate mechanisms such as audio or video tape or telephone transmission.

"MPJE" means Multistate Pharmacy Jurisprudence Examination.

"NABP" means National Association of Boards of Pharmacy.

"NABPLEX" means National Association of Boards of Pharmacy Licensure Examination.

"NAPLEX" means North American Pharmacist Licensure Examination.

"Other designated personnel" means a non-pharmacist individual who is permitted in the pharmacy area, for a limited time, under the direct supervision of a pharmacist, to perform non-pharmacy related duties, such as trash removal, floor maintenance, and telephone or computer repair.

"Outpatient" means an individual who is not a residential patient in a health care institution.

"Outpatient setting" means a location that provides medical treatment to an outpatient.

"Patient profile" means a readily retrievable, centrally located information record that contains patient demographics, allergies, and medication profile.

"Pharmaceutical patient care services" means the provision of drug selection, drug utilization review, drug administration, drug therapy monitoring, and other drug-related patient care services intended to achieve outcomes related to curing or preventing a disease, eliminating or reducing a patient's symptoms, or arresting or slowing a disease process, by identifying and resolving or preventing potential and actual drug-related problems.

"Pharmacy counter working area" means a clear and continuous working area that contains no major obstacles such as a desktop computer, computer monitor, computer keyboard, external computer drive device, printer, facsimile machine, pharmacy balance, typewriter, or pill-counting machine, but may contain individual documents or prescription labels, pens, prescription blanks, refill log, pill-counting tray, spatula, stapler, or other similar items necessary for the prescription-filling process.

"Pharmacy law continuing education" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations, offered by an Approved Provider.

"Prepackaged drug" means a drug that is packaged in a frequently prescribed quantity, labeled in compliance with A.R.S. §§ 32-1967 and 32-1968, stored, and subsequently dispensed by a pharmacist or a graduate intern or pharmacy intern under the supervision of a pharmacist, who verifies at the time of dispensing that the drug container is properly labeled, in compliance with A.R.S. § 32-1968, for the patient.

"Provider pharmacy" means a pharmacy that contracts with a long-term care facility to supply prescription medication or other services for residents of a long-term care facility.

"Radiopharmaceutical" means any drug that emits ionizing radiation and includes:

Any nonradioactive reagent kit, nuclide generator, or ancillary drug intended to be used in the preparation of a radiopharmaceutical, but does not include drugs such as carbon-containing compounds or potassium-containing salts, that contain trace quantities of naturally occurring radionuclides; and

Any biological product that is labeled with a radionuclide or intended to be labeled with a radionuclide.

"Radiopharmaceutical quality assurance" means performing and interpreting appropriate chemical, biological, and physical tests on radiopharmaceuticals to determine the suitability of the radiopharmaceutical for use in humans and animals. Radiopharmaceutical quality assurance includes internal test assessment, authentication of product history, and appropriate record retention.

"Radiopharmaceutical services" means procuring, storing, handling, compounding, preparing, labeling, quality assurance testing, dispensing, distributing, transferring, recordkeeping, and disposing of radiochemicals, radiopharmaceuticals, and ancillary drugs. Radiopharmaceutical services include quality assurance procedures, radiological health and safety procedures, consulting activities associated with the use of radiopharmaceuticals, and any other activities required for the provision of pharmaceutical care.

"Red C stamp" means a device used with red ink to imprint an invoice with a red letter C at least one inch high, to make an invoice of a Schedule III through IV controlled substance, as defined in A.R.S. § 36-2501, readily retrievable, as required by state and federal rules.

"Remodel" means to alter structurally the pharmacy area or location.

"Remote drug storage area" means an area that is outside the premises of the pharmacy, used for the storage of drugs, locked to deny access by unauthorized persons, and secured against the use of force.

"Resident" means a person admitted to and residing in a long-term care facility.

"Responsible person" means the owner, manager, or other employee who is responsible to the Board for a permitted establishment's compliance with the laws and administrative rules of this state and of the federal government pertaining to distribution of drugs, devices, precursor chemicals, and regulated chemicals. Nothing in this definition relieves other individuals from the responsibility to comply with state and federal laws and administrative rules.

"Score transfer" means the process that enables an applicant to take the NAPLEX in a jurisdiction and be eligible for licensure by examination in other jurisdictions.

"Sight-readable" means that an authorized individual is able to examine a record and read its information from a CRT, microfiche, microfilm, printout, or other method acceptable to the Board or its designee.

"Single-drug audit" means an accounting method that determines the numerical and percentage difference between a drug's beginning inventory plus purchases and ending inventory plus sales.

"Single-drug usage report" means a computer system printout of original and refill prescription order usage information for a single drug.

"Sterile pharmaceutical product" means a dosage form free from living micro-organisms.

"Strength" means:

The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis); or

The potency, that is, the therapeutic activity of a drug substance as indicated by bioavailability tests or by controlled clinical data (expressed, for example, in terms of unity by reference to a standard).

"Supervision" means a pharmacist is present, assumes legal responsibility, and has direct oversight of activities relating to acquiring, preparing, distributing, and selling prescription medications by pharmacy interns, graduate interns, pharmacy technicians, or certified pharmacy technicians and when used in connection with the intern training requirements means that, in a pharmacy where intern training occurs, a pharmacy intern preceptor assumes the primary responsibility of teaching the intern during the entire period of the training.

"Supervisory physician" means a physician licensed under A.R.S. Title 32 Chapter 13 or 17 who:

Writes an order in a patient's medical record and signs a drug therapy management agreement authorizing a pharmacist to provide patient-specific drug therapy management, and

Assumes responsibility for the on-going supervision and evaluation of the drug therapy management performed by the pharmacist.

"Supplying" means selling, transferring, or delivering to a patient or a patient's agent one or more doses of:

A nonprescription drug in the manufacturer's original container for subsequent use by the patient, or

A compressed medical gas in the manufacturer's or compressed medical gas distributor's original container for subsequent use by the patient.

"Support personnel" means an individual, working under the supervision of a pharmacist, trained to perform clerical duties associated with the practice of pharmacy, including cashiering, bookkeeping, pricing, stocking, delivering, answering nonprofessional telephone inquiries, and documenting third-party reimbursement. Support personnel shall not perform the tasks of a pharmacist, pharmacy intern, graduate intern, pharmacy technician, or certified pharmacy technician.

"Transfill" means a manufacturing process by which one or more compressed medical gases are transferred from a bulk container to a properly labeled container for subsequent distribution or supply.

"Wholesale distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:

Selling, purchasing, or trading a drug or offering to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this Section, "emergency medical reasons" includes transferring a prescription drug by a community or hospital pharmacy to another community or hospital pharmacy to alleviate a temporary shortage;

Selling, purchasing, or trading a drug, offering to sell, purchase, or trade a drug, or dispensing a drug as specified in a prescription;

Distributing a drug sample by a manufacturers' or distributors' representative; or

Selling, purchasing, or trading blood or blood components intended for transfusion.

"Wholesale distributor" means any person engaged in wholesale distribution of drugs, including: manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions in the amount of at least 5% of gross sales.

Historical Note

Adopted effective August 24, 1992 (Supp. 92-2). Amended effective December 18, 1992 (Supp. 92-4). Amended effective November 1, 1993 (Supp. 93-4). Amended effective April 1, 1995; filed with the Secretary of State January 31, 1995 (Supp. 95-1). Amended effective April 5, 1996 (Supp. 96-2). Amended effective July 8, 1997; amended effective August 5, 1997 (Supp. 97-3). Amended effective January 12, 1998 (Supp. 98-1). Amended effective July 7, 1998 (Supp. 98-3). Amended by final rulemaking at 5 A.A.R. 862, effective March 3, 1999 (Supp. 99-1). Amended by final rulemaking at 5 A.A.R. 4441, effective November 2, 1999 (Supp. 99-4). Amended by final rulemaking at 6 A.A.R. 4589, effective November 14, 2000 (Supp. 00-4). Amended by final rulemaking at 7 A.A.R. 646, effective January 11, 2001 (Supp. 01-1). Amended by final rulemaking at 8 A.A.R. 409 and 8 A.A.R. 646, effective January 10, 2002 (Supp. 02-1). Amended by final rulemaking at 8 A.A.R. 416, effective January 10, 2002 (Supp. 02-1). Amended by final rulemaking at 8 A.A.R. 1256, effective March 7, 2002 (Supp. 02-1). Amended by final rulemaking at 8 A.A.R. 4052, effective November 9, 2002 (Supp. 02-3). Amended by final rulemaking at 8 A.A.R. 4898 and 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4). Amended by final rulemaking at 9 A.A.R. 1064, effective May 4, 2003 (Supp. 03-1). Amended by final rulemaking at 9 A.A.C. 5030, effective January 3, 2004 (Supp. 03-4). Amended by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-111. Notice of Hearing

A. Except as provided in A.R.S. § 32-1928(B), the Board shall revoke, suspend, place on probation, or fine a licensee or permittee only after:
1. Notice is served under this Section, and
2. A hearing is conducted under R4-23-122.

B. The Board shall give notice of hearing to a party at least 30 days before the date set for the hearing in the manner described in R4-23-115(E) and (F). The notice shall include:
1. A statement of the date, time, place, and nature of the hearing;
2. A statement of the legal authority and jurisdiction for the hearing;
3. A reference to the particular section or sections of statute and rule involved; and
4. A statement of the violation or issue asserted by the Board.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-112. Ex Parte Communications

A party shall not communicate, either directly or indirectly, with a Board member about any substantive issue in a pending matter unless:
1. All parties are present;
2. It is during a scheduled proceeding, where an absent party fails to appear after proper notice; or
3. It is by written motion with copies to all parties.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-113. Motions

A. Purpose. A party requesting a ruling from the Board shall file a motion. Motions may be made for rulings such as:
1. Continuing or expediting a hearing under R4-23-116;
2. Vacating a hearing under R4-23-117;
3. Scheduling a prehearing conference under R4-23-118;
4. Quashing a subpoena under R4-23-119;
5. Requesting telephonic testimony under R4-23-120; and
6. Reconsidering a previous order under R4-23-121.

B. Form. Unless made during a prehearing conference or hearing, motions shall be made in writing and shall conform to the requirements of R4-23-115. All motions, whether written or oral, shall state the factual and legal grounds supporting the motion, and the requested action.

C. Time limits. Absent good cause, or unless otherwise provided by law or these rules, written motions shall be filed with the Board office at least 15 days before the hearing. A party demonstrates good cause by showing that the grounds for the motion could not have been known in time, using reasonable diligence and:
1. A ruling on the motion will further administrative convenience, expedition or economy; or
2. A ruling on the motion will avoid undue prejudice to any party.

D. Response to motion. A party shall file a written response stating any objection to the motion within five days of service, or as directed by the Board.

E. Oral argument. A party may request oral argument when filing a motion or response. If necessary to develop a complete record, the Board shall grant oral argument.

F. Rulings. Rulings on motions, other than those made during a prehearing conference or the hearing, shall be in writing and served on all parties.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-114. Computing Time

In computing any time period, the Board shall exclude the day from which the designated time period begins to run. The Board shall include the last day of the period unless it falls on a Saturday, Sunday, or legal holiday. When the time period is 10 days or less, the Board shall exclude Saturdays, Sundays, and legal holidays.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-115. Filing Documents

A. Docket. The Board shall open a docket for each hearing. All documents filed in a matter with the Board shall be date

stamped on the day received by the Board office and entered in the docket.

B. Definition. "Documents" include papers such as complaints, answers, motions, responses, notices, and briefs.

C. Form. A party shall state on the document the name and address of each party served and how service was made under subsection (E). A document shall contain the Board caption and the Board's docket number.

D. Signature. A document filed with the Board shall be signed by the party or the party's attorney. A signature constitutes a certification that the signer has read the document, has a good faith basis for submission of the document, and that it is not filed for the purpose of delay or harassment.

E. Filing and service. A copy of a document filed with the Board shall be served on all parties. Filing with the Board office and service shall be completed by personal delivery; first-class, certified, or express mail; or facsimile.

F. Date of filing and service. A document is filed with the Board on the date it is received by the Board office, as established by the Board office's date stamp on the face of the document. A copy of a document is served on a party as follows:
1. On the date it is personally served,
2. Five days after it is mailed by first-class or express mail,
3. On the date of the return receipt if it is mailed by certified mail, or
4. On the date indicated on the facsimile transmission.

Historical Note
New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-116. Continuing or Expediting a Hearing; Reconvening a Hearing

A. Continuing or expediting a hearing. When ruling on a motion to continue or expedite, the Board shall consider such factors as:
1. The time remaining between the filing of the motion and the hearing date;
2. The position of other parties;
3. The reasons for expediting the hearing or for the unavailability of the party, representative, or counsel on the date of the scheduled hearing;
4. Whether testimony of an unavailable witness can be taken telephonically or by deposition; and
5. The status of settlement negotiations.

B. Reconvening a hearing. The Board may recess a hearing and reconvene at a future date by a verbal ruling.

Historical Note
New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-117. Vacating a Hearing

The Board shall vacate a calendared hearing and return the matter to the Board office for further action, if:
1. The parties agree to vacate the hearing;
2. The Board dismisses the matter;
3. The non-Board party withdraws the appeal; or
4. Facts demonstrate to the Board that it is appropriate to vacate the hearing for the purpose of informal disposition, or if the action will further administrative convenience, expedition, and economy and does not conflict with law or cause undue prejudice to any party.

Historical Note
New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-118. Prehearing Conference

A. Procedure. The Board may hold a prehearing conference. The conference may be held telephonically. The Board may issue a prehearing order outlining the issues to be discussed.

B. Record. The Board may record any agreements reached during a prehearing conference by electronic or mechanical means, or memorialize them in an order.

Historical Note
New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-119. Subpoenas

A. Form. A party shall request a subpoena in writing from the Board and shall include:
1. The caption and docket number of the matter;
2. A list or description of any documents sought;
3. The full name and home or business address of the custodian of the documents sought or all persons to be subpoenaed;
4. The date, time, and place to appear or to produce documents pursuant to the subpoena; and
5. The name, address, and telephone number of the party, or the party's attorney, requesting the subpoena.

B. The Board may require a brief statement of the relevance of testimony or documents.

C. Service of subpoena. Any person who is not a party and is at least 18 years of age may serve a subpoena. The person shall serve the subpoena by delivering a copy to the person to be served. The person serving the subpoena shall provide proof of service by filing with the Board office a certified statement of the date and manner of service and the names of the persons served.

D. Objection to subpoena. A party, or the person served with a subpoena who objects to the subpoena, or any portion of it, may file an objection with the Board. The objection shall be filed within five days after service of the subpoena, or at the outset of the hearing if the subpoena is served fewer than five days before the hearing.

E. Quashing, modifying subpoenas. The Board shall quash or modify a subpoena if:
1. It is unreasonable or oppressive, or
2. The desired testimony or evidence may be obtained by an alternative method.

Historical Note
New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-120. Telephonic Testimony

The Board may grant a motion for telephonic testimony if:
1. Personal attendance by a party or witness at the hearing will present an undue hardship for the party or witness;
2. Telephonic testimony will not cause undue prejudice to any party; and
3. The proponent of the telephonic testimony pays for any cost of obtaining the testimony telephonically.

Historical Note
New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-121. Rights and Responsibilities of Parties

A. Generally. A party may present testimony and documentary evidence and argument with respect to the contested issue and may examine and cross-examine witnesses.

B. Preparation. A party shall have all witnesses, documents, and exhibits available on the date of the hearing.

C. Exhibits. A party shall provide a copy of each exhibit to all other parties at the time the exhibit is offered to the Board, unless the exhibit was previously provided to all other parties.

D. Responding to orders. A party shall comply with an order issued by the Board concerning the conduct of a hearing. Unless an objection is made orally during a pre-hearing conference or hearing, a party shall file a motion requesting the Board to reconsider the order.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-122. Conduct of Hearing

A. Public access. Unless otherwise provided by law, all hearings are open to the public and may be conducted in an informal manner as prescribed in A.R.S. § 41-1092 et seq.

B. Opening. The Board shall begin the hearing by reading the caption, stating the nature and scope of the hearing, and identifying the parties, counsel, and witnesses for the record.

C. Stipulations. The Board shall enter into the record any stipulation, settlement agreement, or consent order entered into by any of the parties before or during the hearing.

D. Opening statements. The party with the burden of proof may make an opening statement at the beginning of a hearing. All other parties may make statements in a sequence determined by the Board.

E. Order of presentation. After opening statements, the party with the burden of proof shall begin the presentation of evidence, unless the parties agree otherwise or the Board determines that requiring another party to proceed first would be more expeditious or appropriate, and would not prejudice any other party. Copies of documentary evidence may be received in the discretion of the Board. Upon request, parties shall be given an opportunity to compare the copy with the original.

F. Examination. A party shall conduct direct and cross examination of witnesses in the order and manner determined by the Board to expedite and ensure a fair hearing. The Board shall make rulings necessary to prevent argumentative, repetitive, or irrelevant questioning and to expedite the examination to the extent consistent with the disclosure of all relevant testimony and information. The Board may take notice of judicially cognizable facts. In addition, the Board may take notice of generally recognized technical or scientific facts within the Board's or its staff's specialized knowledge. A party shall be notified either before or during the hearing or by reference in preliminary reports of the material the Board notices. The Board may use the Board's or its staff's experience, technical competence, and specialized knowledge in the evaluation of the evidence.

G. Closing argument. When all evidence has been received, parties shall have the opportunity to present closing oral argument, in a sequence determined by the Board. The Board may permit or require closing oral argument to be supplemented by written memoranda. The Board may permit or require written memoranda to be submitted simultaneously or sequentially, within time periods the Board may prescribe.

H. Conclusion of hearing. Unless otherwise provided by the Board, the hearing is concluded upon the submission of all evidence, the making of final argument, and the issuing of a final decision or order of the Board.

I. Decisions and orders. Unless otherwise provided by law, any final decisions or order adverse to a party in a hearing shall be in writing or stated in the record. Any final decision shall include findings of fact and conclusions of law, separately stated. Findings of fact shall be accompanied by a concise and explicit statement of the underlying facts supporting the findings. Unless otherwise provided by law, each party shall be notified either personally or by mail to the party's last known address of record of any decision or order. Upon request, a copy of the decision or order shall be delivered or mailed to each party and to each party's attorney of record.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-123. Failure of Party to Appear for Hearing

If a party fails to appear at a hearing, the Board may proceed with the presentation of the evidence of the appearing party, or vacate the hearing and return the matter to the Board office for any further action.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-124. Witnesses; Exclusion from Hearing

All witnesses at the hearing shall testify under oath or affirmation. At the request of a party, or at the discretion of the Board, the Board may exclude witnesses who are not parties from the hearing room so that they cannot hear the testimony of other witnesses.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-125. Proof

A. Standard of proof. Unless otherwise provided by law, the standard of proof is a preponderance of the evidence.

B. Burden of proof. Unless otherwise provided by law:

1. The party asserting a claim, right, or entitlement has the burden of proof;
2. A party asserting an affirmative defense has the burden of establishing the affirmative defense; and
3. The proponent of a motion shall establish the grounds to support the motion.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-126. Disruptions

A person shall not interfere with access to or from the hearing room, or interfere, or threaten interference with the hearing. If a person interferes, threatens interference, or disrupts the hearing, the Board may order the disruptive person to leave or be removed.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-127. Hearing Record

A. Maintenance. The Board shall maintain the official administrative record of a matter.

B. Transfer of record. Any party requesting a copy of the administrative record or any portion of the administrative record shall make a request to the Board office and shall pay the reasonable costs of duplication.

C. Release of exhibits. Exhibits shall be released:

1. Upon the order of a court of competent jurisdiction; or
2. Upon motion of the party who submitted the exhibits if the time for judicial appeal has expired and no appeal is pending.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-128. Rehearing or Review and Appeal of Decision

A. The Board shall provide for a rehearing and review of it decisions under A.R.S. Title 41, Chapter 6, Article 10, and this Section. For purposes of these rules, the terms "contested case" and "party" are defined in A.R.S. § 41-1001.

B. A party to a contested case shall exhaust the party's administrative remedies by filing a motion for rehearing or review within 30 days after the service of the Board decision that is subject to rehearing or review in order to be eligible for judicial review under A.R.S. Title 12, Chapter 7, Article 6. The Board shall notify a party in its decision, that is subject to rehearing or review, that the party may file a motion for rehearing or review, and that failure to file a motion for rehearing or review within 30 days after service of the decision has the effect of prohibiting the party from seeking judicial review of the Board's decision.

C. A party may amend a motion for rehearing or review at any time before the Board rules on the motion.

D. The Board may grant a rehearing or review for any of the following reasons materially affecting a party's rights:
1. Irregularity in the proceedings of the Board, or any order or abuse of discretion, that deprived the moving party of a fair hearing;
2. Misconduct of the Board, its staff, its hearing officer, or the prevailing party;
3. Accident or surprise that could not have been prevented by ordinary prudence;
4. Newly discovered material evidence that could not, with reasonable diligence, have been discovered and produced at the hearing;
5. Excessive or insufficient penalty;
6. Error in the admission or rejection of evidence or other errors of law occurring at the hearing or during the progress of the proceedings;
7. That the Board's decision is a result of passion or prejudice; or
8. That the findings of fact or decision is not justified by the evidence or is contrary to law.

E. The Board may affirm or modify a decision or grant a rehearing to all or any of the parties on all or part of the issues for any of the reasons in subsection (D). An order modifying a decision or granting a rehearing shall specify with particularity the grounds for the order.

F. If a motion for rehearing or review is based upon affidavits, they shall be served with the motion. An opposing party may, within 15 days after service, serve opposing affidavits. The Board may extend this period for a maximum of 20 days, for good cause as described in subsection (I).

G. Not later than 10 days after the date of a decision, after giving parties notice and an opportunity to be heard, the Board may grant a rehearing or review on its own initiative for any reason for which it might have granted relief on the motion of a party. The Board may grant a motion for rehearing or review, timely served, for a reason not stated in the motion.

H. If a rehearing is granted, the Board shall hold the rehearing within 60 days after the order granting the rehearing is issued.

I. The Board may extend all time limits listed in this Section upon a showing of good cause. A party demonstrates good cause by showing that the grounds for the party's motion or other action could not have been known in time, using reasonable diligence, and a ruling on the motion will:
1. Further administrative convenience, expedition, or economy; or
2. Avoid undue prejudice to any party.

Historical Note
New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

R4-23-129. Notice of Judicial Appeal; Transmitting the Transcript

A. Notification to the Board office. Within 10 days of filing a complaint for judicial review of a final administrative decision of the Board, the party shall file a copy of the complaint with the Board office. The Board office shall then transmit the administrative record to the Superior Court.

B. Transcript. A party requesting a transcript shall arrange for transcription at the party's expense. The Board office shall make a copy of the audio taped record available to the transcriber. The party arranging for transcription shall deliver the transcript, certified by the transcriber under oath to be a true and accurate transcription of the audio taped record, to the Board office, together with one unbound copy.

Historical Note
New Section made by final rulemaking at 10 A.A.R. 1132, effective May 1, 2004 (Supp. 04-1).

ARTICLE 2. PHARMACIST LICENSURE

R4-23-201. General

A. Licensure required: Before posing or practicing as a pharmacist in Arizona, a person shall possess a valid pharmacist license issued by the Board. There is no temporary licensure.

B. Methods of licensure: Licensure as a pharmacist shall be either:
1. By practical examination, using paper and pencil written testing, computer adaptive testing, or other Board-approved testing methods; or
2. By reciprocity.

C. Practicing pharmacist holding a delinquent license: Before an Arizona pharmacist license will be reinstated, a pharmacist, whose Arizona pharmacist license is delinquent for five or more years and who is practicing pharmacy outside the Board's jurisdiction with a pharmacist license issued by another jurisdiction, shall:
1. Pass the AZPLEX or other Board-approved jurisprudence examination,
2. Pay all delinquent annual renewal fees, and
3. Pay penalty fees.

D. Non-practicing pharmacist holding a delinquent license: Before an Arizona pharmacist license will be reinstated, a pharmacist, whose Arizona pharmacist license is delinquent for five or more years and who did not practice pharmacy within the last year, shall complete the requirements in subsection (C) and appear before the Board to furnish satisfactory proof of fitness to be licensed as a pharmacist.

Historical Note
Former Rules 2.1100, 2.1310, 2.1320, and 2.1400. Amended effective August 23, 1978 (Supp. 78-4). Amended by deleting subsection (E) effective April 20, 1982 (Supp. 82-2). Amended subsections (C) and (D) effective August 12, 1988 (Supp. 88-3). Amended effective February 8, 1991 (Supp. 91-1). Amended effective January 12, 1998 (Supp. 98-1).

R4-23-202. Licensure by Examination

A. Eligibility. To be eligible for licensure as a pharmacist by examination, a person shall:
1. Have an undergraduate degree in pharmacy from a school or college of pharmacy whose professional degree program, at the time the person graduates, is accredited by the American Council on Pharmaceutical Education; or
2. Qualify under the requirements of A.R.S. § 32-1922(C); and

3. Complete not less than 1500 hours of intern training as specified in R4-23-303.

B. Application.

1. An applicant for licensure by examination shall file with the Board office:
   a. A completed application for licensure by examination form,
   b. A completed NAPLEX registration form or ensure receipt of an official NABP score transfer report through the Board office online computer link with NABP indicating the applicant's score on the NAPLEX taken in another jurisdiction, and
   c. A completed AZPLEX registration form.
2. The Board office shall deem an application or registration form received on the date that the Board office stamps on the form as the form is delivered to the Board office. The Board office shall deem a score transfer received on the date that the NABP transmits the applicant's official NABP score transfer report through the online computer link to the Board office.
3. An applicant for licensure by examination shall:
   a. Make application on a form furnished by the Board, and
   b. Submit with the application for licensure by examination form:
      i. The documents specified in the application form, and
      ii. The examination fee specified in R4-23-205(C) made payable to the Arizona State Board of Pharmacy by money order or certified or personal check.
4. An applicant for licensure by examination shall:
   a. Make NAPLEX and AZPLEX registration on forms furnished by the Board or NABP; and
   b. Submit with the registration forms:
      i. The documents specified in the registration forms; and
      ii. The examination fee specified by and made payable to NABP by money order, certified check, or bank draft.
5. The Board shall deem an application for licensure by examination or a NAPLEX or AZPLEX registration to be invalid after 12 months from the date the Board office determines an application or registration form is complete. An applicant whose application or registration form is invalid and who wishes to continue licensure procedures, shall submit a new application or registration form and fee.

C. Passing grade; notification; re-examination.

1. To pass the required examinations, an applicant shall obtain a score of at least 75 on both the NAPLEX and AZPLEX.
2. The Board office shall:
   a. Retrieve an applicant's NAPLEX and AZPLEX score from the NABP online database no later than two weeks after the applicant's examination date; and
   b. Mail an applicant's NAPLEX and AZPLEX score to the applicant no later than seven days after the Board office receives the applicant's score from NABP.
3. An applicant who fails the NAPLEX or AZPLEX may apply to retake the examination within the 12-month period defined in subsection(B)(5). An applicant applying to retake an examination shall submit to the Board office a completed NAPLEX or AZPLEX registration form and pay the examination fee specified by and made payable to NABP by money order, certified check, or bank draft. An applicant who fails the NAPLEX or AZPLEX three times shall petition the Board for permission before retaking the examination.

D. NAPLEX score transfer.

1. An applicant who receives a passing score on the NAPLEX taken in another jurisdiction shall, within 12 months from the date the Board office receives the applicant's official NABP score transfer report from the NABP, make application for licensure according to subsection (B). After 12 months, an applicant may reapply for licensure in this state under the provisions of subsection (B) or R4-23-203(B).
2. An applicant who takes the NAPLEX in another jurisdiction and fails the examination may apply for licensure in this state under the provisions of subsection (B).

E. Licensure. The Board office shall issue a certificate of licensure to a successful applicant upon receipt of the licensure fee specified in R4-23-205(A)(1)(a). The Board office shall:

1. Provide a receipt for payment of the licensure fee to an applicant who delivers a payment in person, or
2. Mail a receipt for payment of the licensure fee to an applicant within one working day of receiving the payment by mail or other delivery service.

F. Time-frames for licensure by examination.

1. The Board office shall complete an administrative completeness review within 20 days from the date of receipt of an application or registration form.
   a. The Board office shall issue a written notice of administrative completeness to the applicant if no deficiencies are found in the application or registration form.
   b. If the application or registration form is incomplete, the Board office shall provide the applicant with a written notice that includes a comprehensive list of the missing information. The 20-day time-frame for the Board office to finish the administrative completeness review is suspended from the date the notice of incompleteness is served until the applicant provides the Board office with all missing information.
   c. If the Board office does not provide the applicant with notice regarding administrative completeness, the application or registration form shall be deemed complete 20 days after receipt by the Board office.
2. An applicant with an incomplete application or registration form shall submit all of the missing information within 30 days of service of the notice of incompleteness.
   a. If an applicant cannot submit all missing information within 30 days of service of the notice of incompleteness, the applicant may send a written request for an extension to the Board office post marked or delivered no later than 30 days from service of the notice of incompleteness.
   b. The written request for an extension shall document the reasons the applicant is unable to meet the 30-day deadline.
   c. The Board office shall review the request for an extension of the 30-day deadline and grant the request if the Board office determines that an extension of the deadline will enable the applicant to assemble and submit the missing information. An extension shall be for no more than 30 days. The Board office shall notify the applicant in writing of its decision to grant or deny the request for an extension. An applicant who requires an additional exten-

sion shall submit an additional written request in accordance with this subsection.

3. If an applicant fails to submit a complete application or registration form within the time allowed, the Board office shall close the applicant's file. An applicant whose file is closed and who later wishes to obtain a license shall apply again in accordance with subsection (B).
4. The Board office shall complete a substantive review of the applicant's qualifications in no more than 20 days from the date on which the administrative completeness review of an application or registration form is complete.
   a. If an applicant is found to be ineligible for licensure by examination, the Board office shall issue a written notice of denial to the applicant.
   b. If an applicant is found to be eligible to take the NAPLEX, the Board office shall issue a written notice of eligibility to the applicant and the NABP.
   c. If an applicant is found to be eligible to take the AZPLEX, the Board office shall issue a written notice of eligibility to the applicant and the NABP.
   d. If the Board office finds deficiencies during the substantive review of an application or registration form, the Board office shall issue a written request to the applicant for additional documentation.
   e. The 20-day time-frame for a substantive review of eligibility to take the NAPLEX or AZPLEX is suspended from the date of a written request for additional documentation until the date that all documentation is received. The applicant shall submit the additional documentation in accordance with subsection (F)(2).
   f. If the applicant and the Board office mutually agree in writing, the 20-day substantive review time-frame may be extended once for no more than 10 days.
5. For the purpose of A.R.S. § 41-1072 et seq., the Board establishes the following time-frames for licensure by examination.
   a. Administrative completeness review time-frame: 20 days.
   b. Substantive review time-frame: 20 days.
   c. Overall time-frame: 40 days.

Historical Note

Former Rules 2.2100, 2.2200, 2.2300, 2.2400, 2.2500, 2.2600, 2.2700, 2.2800, 2.2910, 2.2920, 2.2930, 2.3000, 2.3010, 2.3100; Amended effective August 23, 1978 (Supp. 78-5). Amended effective June 10, 1981 (Supp. 81-3). Former Section R4-23-202 repealed, new Section R4-23-202 adopted effective July 24, 1985 (Supp. 85-4). Amended effective March 13, 1991 (Supp. 91-1). Amended effective January 12, 1998 (Supp. 98-1). Amended by final rulemaking at 8 A.A.R. 409 and 8 A.A.R. 646, effective January 10, 2002 (Supp. 02-1).

R4-23-203. Licensure by Reciprocity

A. Eligibility. A person is eligible for licensure by reciprocity who:
1. Is licensed as a pharmacist in a jurisdiction that provides reciprocity to Arizona licensees;
2. Has passed the NABPLEX or NAPLEX with a score of 75 or better or was licensed by examination in another jurisdiction having essentially the same standards for licensure as this state at the time the pharmacist was licensed;
3. Provides evidence to the Board of having completed the required secondary and professional education and training specified in R4-23-202(A);
4. Has engaged in the practice of pharmacy for at least one year or has met the internship requirements of Article 3 within the year immediately before the date of application; and
5. Has actively practiced as a pharmacist for 400 or more hours within the last calendar year or has an Arizona graduate intern license and has completed 400 hours of internship training in an approved internship training site.

B. Application.
1. An applicant for licensure by reciprocity shall file with the Board office:
   a. A completed application for licensure by reciprocity form; and
   b. A completed AZPLEX registration form.
2. The Board office shall deem an application or registration form received on the date that the Board office stamps on the application or registration form as the form is delivered to the Board office.
3. An applicant for licensure by reciprocity shall:
   a. Make application on a form furnished by the Board, and
   b. Submit with the application for licensure by reciprocity form:
      i. The documents specified in the application form, and
      ii. The reciprocity and examination fee specified in R4-23-205(B) and (C) and made payable to the Arizona State Board of Pharmacy by money order or certified or personal check.
4. An applicant for licensure by reciprocity shall:
   a. Make AZPLEX registration on a form furnished by the Board or NABP; and
   b. Submit with the registration form:
      i. The documents specified in the registration form; and
      ii. The examination fee specified by and made payable to NABP by money order, certified check, or bank draft.
5. The Board office shall deem an application for licensure by reciprocity form or AZPLEX registration invalid after 12 months from the date the Board office determines an application or registration form is complete. An applicant whose application or registration form is invalid and who wishes to continue licensure procedures, shall submit a new application or registration form and fee.

C. Passing grade; notification; re-examination.
1. To pass the required examination, an applicant shall obtain a score of at least 75 on the AZPLEX.
2. The Board office shall:
   a. Retrieve an applicant's AZPLEX score from the NABP online database no later than two weeks after the applicant's examination date; and
   b. Mail an applicant's AZPLEX score to the applicant no later than seven days after the Board office receives the applicant's score from NABP.
3. An applicant who fails the AZPLEX may apply to retake the examination within the 12-month period specified in subsection (B)(5). An applicant applying to retake an examination shall submit to the Board office a completed AZPLEX registration form and pay the examination fee specified by and made payable to NABP by money order, certified check, or bank draft. An applicant who fails the AZPLEX three times shall petition the Board for permission before retaking the examination.

D. Licensure. The Board office shall issue a certificate of licensure to a successful applicant upon receipt of the licensure fee specified in R4-23-205(A)(1)(a). The Board office shall:
1. Provide a receipt for payment of the licensure fee to an applicant who delivers a payment in person; or
2. Mail a receipt for payment of the licensure fee to an applicant within one working day of receiving the payment by mail or other delivery service.

E. Time-frames for licensure by reciprocity. The Board office shall follow the time-frames established for licensure by examination in R4-23-202(F).

Historical Note

Former Rules 2.4100, 2.4200, 2.4310, 2.4320, 2.4330, 2.4340, 2.4350, 2.4360, 2.4400, 2.4510, 2.4520, 2.4522, 2.4523, 2.4530, 2.4540, 2.4550, 2.4560, 2.4610, 2.4620, and 2.4700; Amended effective August 23, 1978 (Supp. 78-4). Amended subsections (H), (L), (O) through (Q) effective June 10, 1981 (Supp. 81-3). Former Section R4-23-203 repealed, new Section R4-23-203 adopted effective July 24, 1985 (Supp. 85-4). Amended effective March 13, 1991 (Supp. 91-1). Amended effective January 12, 1998 (Supp. 98-1). Amended effective January 12, 1998 (Supp. 98-1). Amended by final rulemaking at 8 A.A.R. 409 and 8 A.A.R. 646, effective January 10, 2002 (Supp. 02-1).

R4-23-204. Continuing Education Requirements

A. General. In accordance with A.R.S. § 32-1925(G), the Board shall not renew a license unless the applicant has, during the two years preceding the application for renewal, participated in 30 contact hours (3.0 CEU's) of continuing education activity sponsored by an Approved Provider as defined in R4-23-110, of which at least three contact hours (0.3 CEU's) are approved courses in pharmacy law. Subject to A.R.S. § 32-1937, a pharmacist licensed for less than 24 months shall obtain continuing education units in an amount determined by multiplying 1.25 hours times the number of months between the date of initial licensure and the next license renewal date.

B. Acceptance of continuing education units (CEU's). The Board shall:
1. Only accept CEU's for continuing education activities sponsored by an Approved Provider;
2. Only accept CEU's accrued during the two-year period immediately before licensure renewal;
3. Not allow CEU's accrued in a biennial renewal period in excess of the 3.0 CEU's required to be carried forward to the succeeding biennial renewal period;
4. Allow a pharmacist who leads, instructs, or lectures to a group of health professionals on pharmacy-related topics in continuing education activities sponsored by an Approved Provider to receive CEU's for a presentation by following the same attendance procedures as any other attender of the continuing education activity; and
5. Not accept as CEU's the performance of normal teaching duties within a learning institution by a pharmacist whose primary responsibility is the education of health professionals.

C. Continuing education records and reporting CEU's. A pharmacist shall:
1. Maintain continuing education records that:
   a. Verify the continuing education activities the pharmacist participated in during the preceding five years; and
   b. Consist of a statement of credit or a certificate issued by an Approved Provider at the conclusion of a continuing education activity;
2. At the time of licensure renewal, attest to the number of CEU's the pharmacist participated in during the renewal period on the biennial renewal form; and
3. When requested by the Board office, submit proof of continuing education participation within 20 days of the request.

D. The Board may revoke, suspend, or place on probation the license of a pharmacist who fails to comply with continuing education participation, recording, or reporting requirements of this Section.

E. A pharmacist who is aggrieved by any decision of the Board or its administrative staff concerning continuing education units may request a hearing before the Board.

Historical Note

Adopted effective September 1, 1981 (Supp. 81-5). Amended effective March 13, 1991 (Supp. 91-1). Amended by final rulemaking at 8 A.A.R. 409 and 8 A.A.R. 646, effective January 10, 2002 (Supp. 02-1).

R4-23-205. Fees

A. Licensure fees:
1. Pharmacist:
   a. Initial licensure [Prorated according to A.R.S. § 32-1925(B)]: $145.
   b. Licensure renewal: $145.
2. Pharmacy or graduate intern:
   a. Initial licensure: $50.
   b. Licensure renewal: $50.
3. Pharmacy technician:
   a. Initial licensure [prorated according to A.R.S. § 32-1925(B)]: $50.
   b. Licensure renewal: $50.
4. Pharmacy technician trainee: $25.

B. Reciprocity fee: $300.

C. Application fee: $50.

D. Vendor permit fees (Resident and nonresident):
1. Pharmacy: $400 biennially (Including hospital, and limited service).
2. Drug wholesaler or manufacturer:
   a. Manufacturer: $1000 biennially.
   b. Full-service drug wholesaler: $1000 biennially.
   c. Nonprescription drug wholesaler: $500 biennially.
3. Drug packager or repackager: $1000 biennially.
4. Nonprescription drug, retail:
   a. Category I (30 or fewer items): $100 biennially
   b. Category II (more than 30 items): $200 biennially
5. Compressed medical gas distributor: $200 biennially
6. Compressed medical gas supplier: $100 biennially

E. Other Fees:
1. Wall license.
   a. Pharmacist: $20.
   b. Pharmacy or graduate intern: $10.
   c. Pharmacy technician: $10.
   d. Pharmacy technician trainee: $10.
2. Duplicate of any Board-issued license, registration, certificate, or permit: $10.
3. Duplicate current renewal license: $10.

F. Fees are not refunded under any circumstances except for the Board's failure to comply with its established licensure or permit time-frames under R4-23-202 or R4-23-602.

G. Penalty fee. Renewal applications submitted after the expiration date are subject to penalty fees as provided in A.R.S. §§ 32-1925 and 32-1931.
1. Licensees: A fee equal to half the licensee's biennial licensure renewal fee under subsection (A) and not to exceed $350.

2. Permittees: A fee equal to half the permittee's biennial permit fee under subsection (D) and not to exceed $350.

Historical Note
Adopted effective July 24, 1985 (Supp. 84-5). Amended subsection (A) paragraph (1) effective May 20, 1988 (Supp. 88-2). Amended effective August 12, 1988 (Supp. 88-3). Amended effective February 8, 1991 (Supp. 91-1). Amended effective April 1, 1995; filed with the Secretary of State January 31, 1995 (Supp. 95-1). Amended effective January 12, 1998 (Supp. 98-1). Amended by final rulemaking at 6 A.A.R. 4589, effective November 14, 2000 (Supp. 00-4). Amended by final rulemaking at 8 A.A.R. 409 and 8 A.A.R. 646, effective January 10, 2002 (Supp. 02-1). Amended by final rulemaking at 8 A.A.R. 416, effective January 10, 2002 (Supp. 02-1). Amended by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

R4-23-301. Intern Licensure

A. Licensure as a pharmacy intern or graduate intern is for the purpose of complementing the individual's academic or experiential education in preparation for licensure as a pharmacist. An applicant may request a waiver of intern licensure requirements by submitting a written request and appearing in person at a Board meeting.

B. The prerequisites for licensure as a pharmacy intern are:
1. Current enrollment, in good standing, in a Board-approved college or school of pharmacy; or
2. Graduation from a college or school of pharmacy that is not approved by the Board; and
3. Proof that the applicant received:
   a. A passing score on the Foreign Pharmacy Graduate Equivalency Examination (FPGEE); or
   b. Acceptance to take the FPGEE; or
4. By order of the Board if the Board determines the applicant needs intern training.

C. If the Board determines that a pharmacy intern licensee stops attending pharmacy school classes before graduation under circumstances indicating the licensee does not intend to continue the licensee's pharmacy education, the licensee shall surrender the pharmacy intern license no later than 30 days after the date of the last attended class. A student re-entering a pharmacy program who wishes to continue internship training shall reapply for pharmacy intern licensure.

D. The prerequisites for licensure as a graduate intern are:
1. Graduate from a Board-approved college or school of pharmacy, and
2. Apply for licensure as a pharmacist by examination or reciprocity, or
3. By order of the Board if the Board determines that the applicant needs intern training.

E. Experiential training. Intern training shall include the activities and services encompassed by the term "practice of pharmacy" as defined in A.R.S. § 32-1901.

F. Out-of-state experiential training. An intern shall receive credit for intern training received outside this state if the Board determines that the intern training requirements of the jurisdiction in which the training was received are equal to the minimum requirements for intern training in this state. An applicant seeking credit for intern training received outside this state shall furnish a certified copy of the records of intern training from:
1. The board of pharmacy or the intern licensing agency of the other jurisdiction where the training was received; or
2. In a jurisdiction without an intern licensing agency, the director of the applicant's Board-approved college or school of pharmacy's experiential training program.

G. Management required to verify intern's qualifications. An owner, manager, or pharmacist-in-charge shall not permit a person to act as a pharmacy or graduate intern until the owner, manager, or pharmacist-in-charge verifies that the person is currently licensed by the Board as a pharmacy or graduate intern.

H. Intern application. An applicant for licensure as a pharmacy intern or graduate intern shall:
1. Ensure that the applicant's college or school of pharmacy provides documentation to the Board of the applicant's current enrollment or graduation; and
2. File an application on a form furnished by the Board, that includes:
   a. Applicant's name, address, mailing address, if different, telephone number, and social security number;
   b. Name and address of college or school of pharmacy attending or attended, degree anticipated or received, and anticipated date or date of graduation;
   c. Whether the applicant has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
   d. Whether the applicant has ever had an intern license revoked, suspended, or denied in this state or any other jurisdiction, and if so, indicate where and when;
   e. A recent photograph of the applicant that is no larger than 2 1/2" x 3" with the applicant's signature on the front;
   f. If the applicant graduated from an unapproved college or school of pharmacy, a verification of acceptance to take the FPGEE or an original Foreign Pharmacy Graduate Equivalency Committee (FPGEC) certification document;
   g. Date signed and applicant's verified signature; and
   h. The initial licensure fee specified in R4-23-205.

I. Licensure. Within seven business days of receipt of a completed application, fees, and other information specified in subsection (H), the Board office shall issue a determination. If the application is complete, the Board office shall issue a license number and mail a current renewal receipt to an applicant. An applicant who is issued a license number may begin practice as a pharmacy intern or graduate intern. The initial licensure fee shall include the issuance of a wall certificate. The Board office shall mail the wall certificate to the licensee within 14 days of issuing the license number.

J. License renewal. An intern license shall be kept in good standing by payment of the biennial renewal fee specified in R4-23-205. If a pharmacy intern fails to graduate from a Board-approved college or school of pharmacy within six years from the date the Board issues the intern license, the intern is not eligible for relicensure as an intern unless the intern obtains Board approval as specified in A.R.S. § 32-1923(E). If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925, the intern license is suspended and the licensee shall pay a penalty as provided in A.R.S. § 32-1925 to vacate the suspension.

K. Notification of training.
1. A pharmacy intern who is employed as an intern outside the experiential training program of a Board-approved

college or school of pharmacy or a graduate intern shall notify the Board within ten days of starting or terminating training, or changing training site.

2. The director of a Board-approved college or school of pharmacy's experiential training program shall provide the Board an intern training report as specified in R4-23-304(B)(3).

Historical Note

Former Rules 3.1000, 3.1100, 3.1200, 3.2000, 3.2100, and 3.2200; Amended effective August 23, 1978 (Supp. 78-4). Amended effective April 20, 1982 (Supp. 82-2). Amended subsections (A), (F) and (G) effective August 12, 1988 (Supp. 88-3). Amended effective November 1, 1993 (Supp. 93-4). Amended by final rulemaking at 8 A.A.R. 416, effective January 10, 2002 (Supp. 02-1).

R4-23-302. Training Site and Pharmacy Intern Preceptors

A. To receive credit for intern training hours, a pharmacy or graduate intern shall train in a site that:

1. Holds a valid Arizona pharmacy permit and employs a pharmacy intern preceptor who supervises the intern; or
2. Is an alternative training site. For purposes of this Section, the term alternative training site is a non-pharmacy training site established and monitored by a Board-approved college or school of pharmacy or other non-pharmacy site where pharmacy related activities are performed and where an intern gains experience as specified in R4-23-301(E).

B. The Board shall inform a pharmacy or alternative training site that an intern will not get credit for training received at the site if the Board determines that a pharmacy or alternative training site fails to provide experiential training as specified in R4-23-301(E) or violates A.R.S. Chapter 18 Title 32 or Chapter 27 Title 36 or the federal act.

C. Pharmacy intern preceptor. To be a pharmacy intern preceptor, a pharmacist shall:

1. Hold a current unrestricted pharmacist license;
2. Have a minimum of one year of experience as an actively practicing pharmacist before acting as a pharmacy intern preceptor;
3. If a pharmacist has been found guilty of violating any federal or state law relating to the practice of pharmacy, drug or device distribution or recordkeeping, or unprofessional conduct, enter into an agreement satisfactory to the Board that places restrictions on the pharmacist's license; and
4. Hold a faculty position in the experiential training program of a Board-approved college or school of pharmacy; or
5. Be approved by the Board as being otherwise qualified as a pharmacy intern preceptor.

D. Revocation of preceptorship privileges. The Board shall revoke a pharmacy intern preceptor's privilege to train pharmacy or graduate interns if the Board determines that a pharmacy intern preceptor fails to provide experiential training as specified in R4-23-301(E) or violates A.R.S. Chapter 18 Title 32 or Chapter 27 Title 36 or the federal act. R4-23-104 applies to revocation of preceptor privileges.

E. Pharmacist-intern ratio. A pharmacy intern preceptor may supervise the training of more than one pharmacy or graduate intern during a calendar quarter. The ratio of pharmacist to intern shall not exceed one pharmacist to two interns in a community pharmacy or limited-service pharmacy setting unless approved by the Board. In considering a request to exceed the ratio, the Board will consider pharmacy space limitations and whether exceeding the ratio poses a safety risk to the public health. Subject to R4-23-609 and the safety of public health, there is no pharmacist to intern ratio in a practice setting directed by a Board-approved college or school of pharmacy experiential training program.

F. Preceptor responsibilities. A pharmacy intern preceptor assumes the responsibilities of a teacher and mentor in addition to those of a pharmacist. A preceptor shall thoroughly review pharmacy policy and procedure with each intern. A preceptor is responsible for the pharmacy related actions of an intern during the specific training period. A preceptor shall give an intern the opportunity for skill development and provide an intern with timely and realistic feedback regarding their progress.

Historical Note

Former Rules 3.3000, 3.3100, 3.3200, 3.3300, 3.3310, 3.3320, 3.3330, 3.3340, 3.3400, 3.4000, 3.4100, 3.4200, 3.4300, and 3.4400; Amended effective August 9, 1983 (Supp. 83-4). Amended by final rulemaking at 8 A.A.R. 416, effective January 10, 2002 (Supp. 02-1).

R4-23-303. Training Time

A. Training. The minimum hours of internship training required for licensure by examination shall be 1,500. A pharmacy intern shall accumulate all 1500 hours of internship training after enrolling in a college of pharmacy as prescribed in R4-23-301(B) and receiving a Board-issued pharmacy intern license. The Board shall credit a pharmacy intern with no more than 500 hours of internship training per calendar quarter.

B. Start of training and limitation of credit. To receive credit as internship training, the practical experience shall take place in a pharmacy or an alternative training site as specified in R4-23-302(A) and under the supervision of a pharmacy intern preceptor, except for a non-pharmacy site as part of a Board-approved college or school of pharmacy experiential training program. The Board shall credit no more than 500 hours internship training as a pharmacy or graduate intern in an alternative training site specified in R4-23-302(A)(2).

Historical Note

Former Rules 3.5000 and 3.5200; Amended effective August 23, 1978 (Supp. 78-4). Amended effective August 9, 1983 (Supp. 83-4). Amended by final rulemaking at 8 A.A.R. 416, effective January 10, 2002 (Supp. 02-1).

R4-23-304. Reports

A. Change of employment or mailing address. A pharmacy intern or graduate intern shall notify the Board within 10 days of change of employment or mailing address.

B. Quarterly reports.

1. A pharmacy intern who is a graduate of a college or school of pharmacy that is not approved by the Board or is a graduate intern shall provide the Board quarterly intern training reports for the duration of training. A quarterly intern training report shall be filed October 1, January 1, April 1 and July 1 for the preceding quarter, whether the intern was in training or not during the quarter. A quarterly intern training report is delinquent if not received at the Board's office 30 days after the due date. The Board shall write the intern to acknowledge receipt of the reports and notify the intern of the remaining hours of training required. A quarterly intern training report shall include:
   a. Intern's name, address, and license number;
   b. Training site name and address;
   c. Pharmacy intern preceptor's name and license number;

d. Whether the report is for the first quarter (Jan.-Mar.), second quarter (Apr.-June), third quarter (July-Sept.), or fourth quarter (Oct.-Dec.);
e. Number of intern training hours per week, specified by week ending date (month, day, year) and total number of intern training hours for the quarter; and
f. Date signed and pharmacy intern preceptor's signature verifying that the pharmacy intern preceptor has been actively engaged in the practice of pharmacy for at least one year and that the pharmacy intern preceptor supervised the intern training of the pharmacy or graduate intern identified in the quarterly intern training report.

2. A pharmacy intern seeking credit for intern training hours received outside an approved college or school of pharmacy's experiential training program shall provide the Board a quarterly intern training report as specified in subsection (B)(1)
3. After graduation and before sitting for the NAPLEX or AZPLEX, a pharmacy intern who is a graduate of a Board-approved college or school of pharmacy shall ensure that the director of the Board-approved college or school of pharmacy's experiential training program provides the Board an intern training report that includes:
   a. A list of all training sites where training occurred during any part of the entire training program including addresses and telephone numbers;
   b. The dates and number of training hours experienced, by training site and total;
   c. The name of the pharmacy intern preceptor, if applicable, for each training site; and
   d. The date signed and experiential training program director's signature verifying that the pharmacy intern successfully completed the experiential training program.

Historical Note
Former Rules 3.6100, 3.6200, 3.6300, and 3.6400; Amended effective August 23, 1978 (Supp. 78-4). Amended by final rulemaking at 8 A.A.R. 416, effective January 10, 2002 (Supp. 02-1).

R4-23-305. Miscellaneous Intern Training Provisions
To prevent a loss of intern hour credit and before beginning training, an intern may ask the Board if a training site meets the requirements specified in R4-23-301(E) and R4-23-302(A).

Historical Note
Former Rule 3.7000; Amended effective August 23, 1978 (Supp. 78-4). Amended by final rulemaking at 8 A.A.R. 416, effective January 10, 2002 (Supp. 02-1).

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-401. Time-frames for Board Approvals and Special Requests

A. To request a Board approval required by this Chapter or a special request to deviate from or waive compliance with a requirement of this Chapter, a person shall send a letter by regular mail, e-mail, or facsimile to the Board office, detailing the nature of the approval or special request, including the applicable Arizona Revised Statute or administrative code citation. This Section does not apply to a request from a person regarding the probation, suspension, or revocation of a license or permit.

B. The Board office shall complete an administrative completeness review within 15 days from the date of receipt of a written request and immediately open a request file for the applicant.
1. The Board office shall issue a written notice of administrative completeness to the applicant if no deficiencies are found in the request.
2. If the request is incomplete, the Board office shall provide the applicant with a written notice that includes a comprehensive list of the missing information. The 15-day time-frame for the Board office to finish the administrative completeness review is suspended from the date the notice of incompleteness is served until the applicant provides the Board office with all missing information.
3. If the Board office does not provide the applicant with notice regarding administrative completeness, the request is deemed complete 15 days after receipt by the Board office.

C. An applicant with an incomplete request shall submit all of the missing information within 30 days of service of the notice of incompleteness.
1. If an applicant cannot submit all missing information within 30 days of service of the notice of incompleteness, the applicant may send a written request for an extension to the Board office post-marked or delivered no later than 30 days from service of the notice of incompleteness.
2. The written request for an extension shall document the reasons the applicant cannot meet the 30-day deadline.
3. The Board office shall review the request for an extension of the 30-day deadline and grant the request if the Board office determines that an extension of the deadline will enable the applicant to assemble and submit the missing information. An extension shall be for no more than 30 days. The Board office shall notify the applicant in writing of its decision to grant or deny the request for an extension. An applicant who requires an additional extension shall submit an additional written request according to subsections (C)(1) and (C)(2).

D. If an applicant fails to submit a complete request within the time allowed, the Board office shall close the applicant's request file. An applicant whose request file is closed and who later wishes to obtain an approval or special request shall apply again according to subsection (A).

E. From the date on which the administrative completeness review of a request is finished, the Board shall complete a substantive review of the applicant's request in no more than 120 days.
1. The Board shall:
   a. Approve the request,
   b. Deny the request, or
   c. If the Board determines deficiencies exist, request that the applicant produce additional documentation.
2. If the Board approves or denies, the Board office shall issue a written approval or denial.
3. If the Board finds deficiencies during the substantive review of a request, the Board office shall issue a written request to the applicant for additional documentation.
4. The 120-day time-frame for a substantive review of a request for approval or special request is suspended from the date of a written request for additional documentation until the date of the next Board meeting after all documentation is received. The applicant shall submit the additional documentation according to subsection (C).
5. If the applicant and the Board office mutually agree in writing, the 120-day substantive review time-frame may be extended once for no more than 30 days.

F. If the applicant fails to submit the additional information requested within the time allowed, the Board office shall close the applicant's request file. An applicant whose request file is

closed and who later wishes to obtain an approval or special request shall apply again according to subsection (A).

G. For the purpose of A.R.S. § 41-1072 et seq., the Board establishes the following time-frames for a Board approval required by this Chapter or a special request to deviate from or waive compliance with a requirement of this Chapter:
1. Administrative completeness review time-frame: 15 days;
2. Substantive review time-frame: 120 days; and
3. Overall time-frame: 135 days.

Historical Note

Former Rule 4.1000; Former Section R4-23-401 repealed, new Section R4-23-401 adopted effective August 9, 1983 (Supp. 83-4). Amended effective May 16, 1990 (Supp. 90-2). Repealed effective August 24, 1992 (Supp. 92-3). New Section made by final rulemaking at 9 A.A.R. 3184, effective August 30, 2003 (Supp. 03-3).

R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern

A. A pharmacist or a graduate intern or pharmacy intern under the supervision of a pharmacist shall perform the following professional practices in dispensing a prescription medication from a prescription order:
1. Receive, reduce to written form, and manually initial oral prescription orders;
2. Obtain and record the name of an individual who communicates an oral prescription order;
3. Obtain, or assume responsibility to obtain, from the patient, patient's agent, or medical practitioner and record, or assume responsibility to record, in the patient's profile, the following information:
   a. Name, address, telephone number, date of birth (or age), and gender;
   b. Individual history including known diseases and medical conditions, known drug allergies or drug reactions, and if available a comprehensive list of medications currently taken and medical devices currently used;
4. Record, or assume responsibility to record, in the patient's profile, a pharmacist's, graduate intern's, or pharmacy intern's comments relevant to the patient's drug therapy, including other information specific to the patient or drug;
5. Verify the legality and pharmaceutical feasibility of dispensing a drug based upon:
   a. A patients' allergies,
   b. Incompatibilities with a patient's currently-taken medications,
   c. A patient's use of unusual quantities of dangerous drugs or narcotics,
   d. A medical practitioner's signature, and
   e. The frequency of refills;
6. Verify that a dosage is within proper limits;
7. Interpret the prescription order, which includes exercising professional judgment in determining whether to dispense a particular prescription;
8. Compound, mix, combine, or otherwise prepare and package the prescription medication needed to dispense individual prescription orders;
9. Prepackage or supervise the prepackaging of drugs by a pharmacy technician or pharmacy technician trainee under R4-23-1104. For drugs prepackaged by a pharmacy technician or pharmacy technician trainee, a pharmacist shall:
   a. Verify the drug to be prepackaged;
   b. Verify that the label meets the official compendium's standards;
   c. Check the completed prepackaging procedure and product; and
   d. Manually initial the completed label; or
   e. For automated packaging systems, manually initial the completed label or a written log or initial a computer-stored log;
10. Check a prescription label to ensure that it communicates the prescriber's directions precisely;
11. Make a final accuracy check on the completed prescription medication and manually initial the finished label. Manual initialing of a finished label is not required if the pharmacy's computer system complies with the computer documentation requirements of R4-23-408(B)(4);
12. Record, or assume responsibility to record, a prescription serial number and date dispensed on the original prescription order;
13. Obtain, or assume responsibility to obtain, permission to refill a prescription order and record, or assume responsibility to record on the original prescription order:
   a. Date dispensed,
   b. Quantity dispensed, and
   c. Name of medical practitioner or medical practitioner's agent who communicates permission to refill the prescription order;
14. Reduce to written or printed form, or assume responsibility to reduce to written or printed form, a new prescription order received by:
   a. Facsimile,
   b. Computer modem, or
   c. Other means of communication;
15. Verify and manually initial a new prescription order received by:
   a. Facsimile,
   b. Computer modem, or
   c. Other means of communication;
16. Record on the original prescription order the name or initials of the pharmacist, graduate intern, or pharmacy intern who originally dispenses the prescription order; and
17. Record on the original prescription order the name or initials of the pharmacist, graduate intern, or pharmacy intern who dispenses each refill.

B. Only a pharmacist, graduate intern, or pharmacy intern shall provide oral consultation about a prescription medication to a patient or patient's agent in an outpatient setting, including a patient discharged from a hospital. The oral consultation is required whenever the following occurs:
1. The prescription medication has not been previously dispensed to the patient;
2. A new prescription number is assigned to a previously dispensed prescription medication;
3. The prescription medication has not been previously dispensed to the patient in the same strength or dosage form or with the same directions;
4. The pharmacist, through the exercise of professional judgment, determines that oral consultation is warranted; or
5. The patient or patient's agent requests oral consultation.

C. Oral consultation shall include:
1. The name, strength, and dosage form of a prescription medication or prescription-only device;
2. The directions for use;
3. The route of administration; and

4. Special instructions, precautions, or storage requirements.

D. The pharmacist, through the exercise of professional judgment, may provide oral consultation that includes:
1. Common severe adverse effects, interactions, or therapeutic contraindications, and the action required if they occur;
2. Techniques of self-monitoring drug therapy;
3. The duration of the drug therapy;
4. Prescription refill information; and
5. Action to be taken if a dose is missed.

E. Nothing in subsection (B) shall be construed as requiring a pharmacist, graduate intern, or pharmacy intern to provide oral consultation if a patient or patient's agent refuses the consultation.
1. Only a pharmacist, graduate intern, or pharmacy intern shall accept a refusal for consultation.
2. A pharmacist, graduate intern, or pharmacy intern shall document, or assume responsibility to document, a refusal for consultation on the original prescription order or document by alternative methods approved by the Board or its designee.

F. When a prescription is delivered to the patient or patient's agent outside the immediate area of a pharmacy and a pharmacist is not present, the prescription shall be accompanied by written or printed patient medication information that, in addition to the requirements in subsection (C), includes:
1. Approved use for the prescription medication;
2. Possible adverse reactions;
3. Drug-drug, food-drug, or disease-drug interactions;
4. Missed dose information; and
5. Telephone number of the dispensing pharmacy.

G. A prescription medication or prescription-only device, delivered to a patient at a location where a licensed health care professional is responsible for administering the prescription medication to the patient, is exempt from the requirement of subsection (C).

H. A pharmacist, graduate intern, or pharmacy intern shall wear a badge indicating name and title while on duty.

I. Nothing in this Section prevents a hospital pharmacist from accepting a prescription order according to rules pertaining specifically to hospital pharmacies.

Historical Note

Former Rule 4.1100; Amended effective August 10, 1978 (Supp. 78-4). Amended effective August 9, 1983 (Supp. 83-4). Amended effective May 16, 1990 (Supp. 90-2). Amended effective July 7, 1998 (Supp. 98-3). Amended by final rulemaking at 6 A.A.R. 4656, effective November 14, 2000 (Supp. 00-4). Amended by final rulemaking at 9 A.A.C. 5030, effective January 3, 2004 (Supp. 03-4). Amended by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-403. Repealed

Historical Note

Former Rule 4.1200; Amended effective August 10, 1978 (Supp. 78-4). Amended effective March 28, 1980 (Supp. 80-2). Amended effective August 9, 1983 (Supp. 83-4). Section repealed, new Section adopted effective May 16, 1990 (Supp. 90-2). Amended effective November 1, 1993 (Supp. 93-4). Amended by final rulemaking at 5 A.A.R. 4441, effective November 2, 1999 (Supp. 99-4). Section repealed by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-404. Unethical Practices

A. Rebates prohibited. A pharmacist or pharmacy permittee shall not offer, deliver, receive, or accept any unearned rebate, refund, commission, preference, patronage dividend, discount, or other unearned consideration, whether in the form of money or otherwise, as compensation or inducement to refer a patient, client, or customer to any person, except for a rebate or premium paid completely and directly to a patient. A pharmacist or pharmacy permittee shall not:
1. Make payment to a medical practitioner in money or other consideration for a prescription order prescribed by the medical practitioner; or
2. Make payment to a long-term care or assisted living facility or other health care institution in money, discount, rental, or other consideration in an amount above the prevailing rate for:
   a. Prescription medication or devices dispensed or sold for a patient or resident of the facility or institution; or
   b. Drug selection or drug utilization review services, drug therapy management services, or other pharmacy consultation services provided for a patient or resident of the facility or institution.

B. Prescription order-blank advertising prohibited. A pharmacist or pharmacy permittee shall not:
1. Directly or indirectly furnish to a medical practitioner a prescription order-blank that refers to a specific pharmacist or pharmacy in any manner; or
2. Actively or passively participate in any arrangement or agreement where a prescription order-blank is prepared, written, or issued in a manner that refers to a specific pharmacist or pharmacy.

C. Fraudulent claim for service. A pharmacist or pharmacy permittee shall not claim the performance of a service that the pharmacist or pharmacy permittee knows or should know was not performed, such as, claiming to dispense a prescription medication that is not dispensed.

D. Fraudulent claim for a fee. A pharmacist or pharmacy permittee:
1. Shall not claim a fee for a service that is not performed or earned;
2. May divide a prescription order into two or more portions of prescription medication at the request of a patient, or for some other ethical reason, and charge a dispensing fee for the additional service; and
3. Shall not divide a prescription order merely to obtain an additional fee.

E. Prohibiting a prescription-only drug or device from being dispensed over the counter. A pharmacist shall ensure that:
1. A prescription-only drug or device is dispensed only after receipt of a valid prescription order from a licensed medical practitioner;
2. The dispensed prescription-only drug or device is properly prepared, packaged, and labeled according to this Chapter; and
3. The prescription order is filed according to this Chapter.

Historical Note

Former Rules 4.2110, 4.2120, 4.2130, 4.2210, 4.2230, 4.2400, 4.2500, 4.2600, 4.4100, 4.4200, 4.4310, 4.4320, 4.4400, and 4.4500; Amended effective August 10, 1978 (Supp. 78-4); Amended subsection (I) effective August 9, 1983 (Supp. 83-4). Amended by deleting subsections (H) through (M) effective November 18, 1983 (Supp. 83-6). Amended by final rulemaking at 8 A.A.R. 1256, effective March 7, 2002 (Supp. 02-1).

R4-23-405. Change of Responsibility

A pharmacist designated as the pharmacist-in-charge for a pharmacy, manufacturer, or other establishment shall give immediate notice, as defined in R4-23-110, when:

1. The pharmacist's responsibility as a pharmacist-in-charge is terminated; or
2. The pharmacist knows of a pending termination of the pharmacist's responsibility as the pharmacist-in-charge.

Historical Note

Former Rules 4.5100 and 4.5200; Amended effective August 9, 1983 (Supp. 83-4). Amended effective February 8, 1991 (Supp. 91-1). Amended effective November 1, 1993 (Supp. 93-4). Amended by final rulemaking at 8 A.A.R. 1256, effective March 7, 2002 (Supp. 02-1).

R4-23-406. Repealed

Historical Note

Adopted as an emergency effective January 10, 1979, pursuant to A.R.S. § 41-1003, valid for only 90 days (Supp. 79-1). Amended as an emergency effective April 2, 1979, pursuant to A.R.S. § 41-1003, valid for only 90 days. Adopted effective April 10, 1979 (Supp. 79-1). Former Section R4-23-406 repealed, new Section R4-23-406 adopted effective August 9, 1983 (Supp. 83-4). Amended effective April 1, 1995; filed with the Secretary of State January 31, 1995 (Supp. 95-1). Amended by final rulemaking at 8 A.A.R. 1256, effective March 7, 2002 (Supp. 02-1). Section repealed by final rulemaking at 10 A.A.R. 230, effective March 6, 2004 (Supp. 04-1).

R4-23-407. Prescription Requirements

A. Prescription orders. A pharmacist shall ensure that:

1. A prescription order dispensed by the pharmacist includes the following information:
   a. Date of issuance;
   b. Name and address of the patient for whom or the owner of the animal for which the drug or device is dispensed;
   c. Drug name, strength, and dosage form or device name;
   d. Name of the drug's or device's manufacturer or distributor if the prescription order is written generically or a substitution is made;
   e. Prescribing medical practitioner's directions for use;
   f. Date of dispensing;
   g. Quantity prescribed and if different, quantity dispensed;
   h. For a prescription order for a controlled substance, the medical practitioner's address and DEA number;
   i. For a written prescription order, the medical practitioner's signature;
   j. For an oral prescription order, the medical practitioner's name and telephone number; and
   k. Name or initials of the dispensing pharmacist;
2. A prescription order is kept by the pharmacist or pharmacy permittee as a record of the dispensing of a drug or device for seven years from the date the drug or device is dispensed, except for a drug or device personally administered by a medical practitioner to the medical practitioner's patient; and
3. The dispensing of a drug or device complies with the packaging requirements of the official compendium and state and federal law.

B. Prescription refills. A pharmacist shall ensure that the following information is recorded on the back of a prescription order when it is refilled:

1. Date refilled,
2. Quantity dispensed,
3. Name or approved abbreviation of the manufacturer or distributor if the prescription order is written generically or a substitution is made, and
4. The name or initials of the dispensing pharmacist.

C. A pharmacist may furnish a copy of a prescription order to the patient for whom it is prescribed or to the authorized representative of the patient if the copy is clearly marked "COPY FOR REFERENCE PURPOSES ONLY" or other similar statement. A copy of a prescription order is not a valid prescription order and a pharmacist shall not dispense a drug or device from the information on a copy.

D. Transfer of prescription order information. For a transfer of prescription order information to be valid, a pharmacy permittee or pharmacist-in-charge shall ensure that:

1. Both the original and the transferred prescription order are maintained for seven years after the last dispensing date.
2. The original prescription order information for a Schedule III, IV, or V controlled substance is transferred only as specified in 21 CFR 1306.25, published April 1, 2001, and no future amendments or editions, incorporated by reference and on file with the Board.
3. The original prescription order information for a non-controlled substance drug is transferred without limitation only up to the number of originally authorized refills.
4. Transfer within Arizona.
   a. The transfer of original prescription order information for a non-controlled substance drug meets the following conditions:
      i. The transfer of information is communicated directly between:
         (1) Two licensed pharmacists,
         (2) A licensed pharmacist and a licensed pharmacy or graduate intern, or
         (3) Two licensed pharmacy or graduate interns;
      ii. The following information is recorded by the transferring pharmacist or pharmacy or graduate intern:
         (1) The word "void" is written on the face of the invalidated original prescription unless it is an electronic or oral transfer and the transferred prescription order information is invalidated in the transferring pharmacy's computer system; and
         (2) The name and identification code, number, or address and telephone number of the pharmacy to which the prescription is transferred, the name of the receiving pharmacist or pharmacy or graduate intern, the date of transfer, and the name of the transferring pharmacist or pharmacy or graduate intern is written on the back of the prescription or entered into the transferring pharmacy's computer system; and
      iii. The following information is recorded by the receiving pharmacist or pharmacy or graduate intern on the transferred prescription order:
         (1) The word "transfer;"
         (2) Date of issuance of the original prescription order;
         (3) Original number of refills authorized on the original prescription order;
         (4) Date of original dispensing;

(5) Number of valid refills remaining and the date of the last refill;
(6) Name and identification code, number, or address, telephone number, and original prescription number of the pharmacy from which the prescription is transferred;
(7) Name of the transferring pharmacist or pharmacy or graduate intern; and
(8) Name of the receiving pharmacist or pharmacy or graduate intern.

b. The transfer of original prescription order information for a Schedule III, IV, or controlled substance meets the following conditions:
i. The transfer of information is communicated directly between two licensed pharmacists;
ii. The following information is recorded by the transferring pharmacist:
(1) The word "void" is written on the face of the invalidated original prescription order unless it is an electronic or oral transfer and the transferred prescription order information is invalidated in the transferring pharmacy's computer system; and
(2) The name, address, and DEA number of the pharmacy to which the prescription is transferred, the name of the receiving pharmacist, the date of transfer, and the name of the transferring pharmacist is written on the back of the prescription order or entered into the transferring pharmacy's computer system; and
iii. The following information is recorded by the receiving pharmacist on the transferred prescription order:
(1) The word "transfer;"
(2) Date of issuance of original prescription order;
(3) Original number of refills authorized on the original prescription order;
(4) Date of original dispensing;
(5) Number of valid refills remaining and the date of the last refill;
(6) Name, address, DEA number, and original prescription number of the pharmacy from which the prescription is transferred;
(7) Name of the transferring pharmacist; and
(8) Name of the receiving pharmacist.

5. Transfer from out-of-state.
a. The transfer of original prescription order information for a non-controlled substance drug meets the conditions in subsections (D)(4)(a)(i) and (D)(4)(a)(iii).
b. The transfer of original prescription order information for a Schedule III, IV, or V controlled substance meets the conditions in subsections (D)(4)(b)(i) and (D)(4)(b)(iii).

6. Electronic transfer. The electronic transfer of original prescription order information meets the following conditions:
a. The electronic transfer is between pharmacies owned by the same company using a common or shared database;
b. The electronic transfer of original prescription order information for a non-controlled substance drug is performed by a pharmacist or a pharmacy or graduate intern, pharmacy technician trainee, or pharmacy technician under the supervision of a pharmacist;
c. The electronic transfer of original prescription order information for a controlled substance is performed between two licensed pharmacists;
d. The electronic transfer of original prescription order information for a non-controlled substance drug meets the following conditions:
i. The transferring pharmacy's computer system:
(1) Invalidates the transferred original prescription order information;
(2) Records the identification code, number, or address of the pharmacy to which the prescription order information is transferred;
(3) Records the name or identification code of the receiving pharmacist, pharmacy or graduate intern, pharmacy technician trainee, or pharmacy technician; and
(4) Records the date of transfer; and
ii. The receiving pharmacy's computer system;
(1) Records that a prescription transfer occurred;
(2) Records the date of issuance of the original prescription order;
(3) Records the original number of refills authorized on the original prescription order;
(4) Records the date of original dispensing;
(5) Records the number of valid refills remaining and the date of the last refill;
(6) Records the identification code, number, or address and original prescription number of the pharmacy from which the prescription is transferred;
(7) Records the name or identification code of the receiving pharmacist or pharmacy or graduate intern, pharmacy technician trainee, or pharmacy technician; and
(8) Records the date of transfer.
e. The electronic transfer of original prescription order information for a controlled substance meets the following conditions:
i. The transferring pharmacy's computer system:
(1) Invalidates the transferred original prescription order information;
(2) Records the identification code, number, or address, and DEA number of the pharmacy to which the prescription order information is transferred;
(3) Records the name or identification code of the receiving pharmacist;
(4) Records the date of transfer; and
(5) Records the name or identification code of the transferring pharmacist; and
ii. The electronic prescription order information received by the computer system of the receiving pharmacy includes the information required in subsection (D)(4)(b)(iii); and
f. In addition to electronic documentation of a transferred prescription order in the computer system, an original prescription order containing the requirements of this Section is filed in compliance with A.R.S. § 32-1964.

Historical Note

Adopted effective November 18, 1983 (Supp. 83-6).

Amended by final rulemaking at 8 A.A.R. 1256, effective March 7, 2002 (Supp. 02-1). Amended by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-408. Computer Records

A. Systems manual. A pharmacy permittee or pharmacist-in-charge shall:
1. Develop and implement policies and procedures for the following operational aspects of a computer system:
   a. Examples of all output documentation provided by the computer system that contains original or refill prescription order or patient profile information;
   b. Steps a pharmacy employee follows when the computer system is not operational due to scheduled or unscheduled system interruption;
   c. Regular and routine backup file procedure and file maintenance;
   d. Audit procedures, personnel code assignments, and personnel responsibilities; and
   e. Quality assurance mechanism for data entry validation;
2. Review biennially and, if necessary, revise the policies and procedures required under these rules;
3. Document the review required under subsection (A)(2);
4. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee; and
5. Make the policies and procedures available within the pharmacy for reference by pharmacy personnel and inspection by the Board or its designee.

B. Computer system data storage and retrieval. A pharmacy permittee or pharmacist-in-charge shall ensure that the computer system is capable of:
1. Producing sight-readable information on all original and refill prescription orders and patient profiles;
2. Providing on-line retrieval (via CRT display or hard-copy printout) of original prescription order information required in A.R.S. § 32-1968(C), R4-23-402(A), and R4-23-407(A);
3. Providing on-line retrieval (via CRT display or hard-copy printout) of patient profile information required in R4-23-402(A);
4. Providing documentation identifying the pharmacist responsible for dispensing each original or refill prescription order, except a pharmacy permittee with a computer system, that is in use before the effective date of this Section that cannot provide documentation identifying the dispensing pharmacist, may continue to use the computer system by providing manual documentation identifying the dispensing pharmacist;
5. Producing a printout of all prescription order information, including a single-drug usage report that contains:
   a. The name of the prescribing medical practitioner;
   b. The name and address of the patient;
   c. The quantity dispensed on each original or refill prescription order;
   d. The date of dispensing for each original or refill prescription order;
   e. The name or identification code of the dispensing pharmacist; and
   f. The serial number of each prescription order; and
6. Providing a printout of requested prescription order information to an individual pharmacy within 72 hours of the request if prescription order information is maintained in a centralized computer record system.

C. A pharmacy permittee or pharmacist-in-charge of a pharmacy that uses a pharmacy computer system:
1. Shall notify the D.E.A. and the Board in writing that original and refill prescription information and patient profiles are stored in a pharmacy computer system;
2. Shall comply with this Section if the pharmacy computer system's refill records are used as an alternative to the manual refill records required in R4-23-407(B);
3. Is exempt from the manual refill recordkeeping requirements of R4-23-407(B), if the pharmacy computer system complies with the requirements of this Section; and
4. Shall ensure that documentation of the accuracy of original and refill information entered into a computer system is provided by each pharmacist using the computer system and kept on file in the pharmacy for seven years from the date of the last refill. Documentation includes one of the following:
   a. A hard-copy printout of each day's original and refill data that:
      i. States original and refill data for prescriptions dispensed by each pharmacist is reviewed for accuracy;
      ii. Includes the printed name of each dispensing pharmacist; and
      iii. Is signed and initialed by each dispensing pharmacist; or
   b. A log book or separate file of daily statements that:
      i. States original and refill data for prescriptions dispensed by each pharmacist is reviewed for accuracy;
      ii. Includes the printed name of each dispensing pharmacist; and
      iii. Is signed and initialed by each dispensing pharmacist.

D. If a pharmacy computer system does not comply with the requirements of subsections (A) and (B), the pharmacy permittee or pharmacist-in-charge shall bring the computer system into compliance within three months of a notice of noncompliance or violation letter. If the computer system is still noncompliant with subsection (A) or (B) after three months, the pharmacy permittee or pharmacist-in-charge shall immediately comply with the manual recordkeeping requirements of R4-23-402 and R4-23-407.

E. If a pharmacy's personnel perform manual recordkeeping under subsection (D), the pharmacy's personnel shall continue manual recordkeeping until the pharmacist-in-charge sends proof, verified by a Board compliance officer, that the computer system complies with subsections (A) and (B).

F. Security. To maintain the confidentiality of patient records, a pharmacy permittee or pharmacist-in-charge shall ensure that:
1. The computer system has security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription order information and patient profiles; and
2. After a prescription order is dispensed, any alteration of prescription order information is documented, including the identification of the pharmacist responsible for the alteration.

G. A computer system that does not comply with all the requirements of subsections (A) and (B) may be used in a pharmacy if:
1. The computer system was in use in the pharmacy before July 11, 2001, and
2. The pharmacy complies with the manual recordkeeping requirements of R4-23-402 and R4-23-407.

Historical Note

Adopted effective November 18, 1983 (Supp. 83-6). Amended by final rulemaking at 7 A.A.R. 646, effective

January 11, 2001 (Supp. 01-1). Amended by final rulemaking at 9 A.A.C. 5030, effective January 3, 2004 (Supp. 03-4).

R4-23-409. Returning Drugs and Devices

A. After a person for whom a drug is prescribed or the person's agent takes the drug from the premises where sold, distributed, or dispensed, a pharmacist or pharmacy permittee shall not accept the drug for return or exchange for the purpose of resale unless the pharmacist determines that:
1. The drug is in its original, manufacturer's, unopened container; and
2. The drug or its container has not been subjected to contamination or deterioration.

B. The provisions of subsection (A) of this Section do not apply to a drug dispensed to:
1. A hospital inpatient as defined in R4-23-651; or
2. A resident of a long-term care facility where a licensed health care professional administers the drug, and the pharmacist ensures and documents that the drug:
   a. Has been stored in compliance with the requirements of the official compendium; and
   b. Is not obviously contaminated or deteriorated.

C. After a person for whom a device is prescribed or the person's agent takes the device from the premises where sold, distributed, or dispensed, a pharmacist or pharmacy permittee shall not accept the device for return or exchange for the purpose of resale or reuse unless the pharmacist determines that:
1. The device is inspected and is free of defects;
2. The device is rendered incapable of transferring disease; and
3. The device, if resold or reused, is not claimed to be new or unused.

Historical Note

Adopted effective November 18, 1983 (Supp. 83-6). Amended by final rulemaking at 8 A.A.R. 1256, effective March 7, 2002 (Supp. 02-1).

R4-23-410. Current Good Compounding Practices

A. This rule establishes the current good compounding practices to be used by a pharmacist licensed by the Board, in a pharmacy permitted by the Board, and in compliance with applicable federal and state law governing the practice of pharmacy.

B. A pharmacy permittee shall ensure compliance with the provisions in this subsection.
1. All drug substances for compounding that are received, sorted, or used by the pharmacy permittee:
   a. Meet official compendium requirements;
   b. Are of high quality, such as Chemically Pure (CP), Analytical Reagent (AR), certified American Chemical Society (ACS), or Food Chemical Codex (FCC) grade; or
   c. Are obtained from a source that, in the professional judgment of the pharmacist, is acceptable and reliable.
2. A pharmacist, employed by the pharmacy permittee, compounds a drug in limited quantity in anticipation of receiving valid prescriptions for the drug, only after establishing a history of compounding valid prescriptions for the drug.
3. Neither the pharmacy permittee nor a pharmacist employed by the pharmacy permittee provides a compounded drug to a pharmacy, medical practitioner, or other person for dispensing or distributing except that a compounded drug may be provided to a medical practitioner to administer to a patient of the medical practitioner.
4. A pharmacy or pharmacist may advertise or otherwise promote the fact that the pharmacy or pharmacist provides prescription compounding services.

C. A pharmacy permittee shall ensure compliance with the organization, training, and personnel issues in this subsection.
1. Before dispensing a compounded drug, a pharmacist:
   a. Inspects and approves or rejects, or assumes responsibility for inspecting and approving or rejecting, components, drug product containers and closures, in-process materials, and labeling;
   b. Prepares or assumes responsibility for preparing all compounding records;
   c. Reviews all compounding records to ensure that no errors occur in the compounding process; and
   d. Ensures the proper use, cleanliness, and maintenance of all compounding equipment.
2. A pharmacist engaged in compounding:
   a. Complies with the current good compounding practices and applicable state pharmacy laws;
   b. Maintains compounding proficiency through current awareness, training, and continuing education; and
   c. Ensures that personnel engaged in compounding wear:
      i. Clean clothing appropriate to the work performed; and
      ii. Protective apparel, such as coats, aprons, gowns, gloves, or masks to protect the personnel from chemical exposure and prevent drug product contamination.

D. A pharmacy permittee shall ensure the security, safety, and quality of a compounded drug by conforming with the following standards:
1. Implement procedures to exclude from direct contact with components, drug product containers and closures, in-process materials, labeling, and drug products, any person with an apparent illness or open lesion that may adversely affect the safety or quality of a compounded drug, until the illness or lesion, as determined by competent medical personnel, does not jeopardize the safety or quality of a compounded drug; and
2. Require all personnel to inform a pharmacist of any health condition that may adversely affect a compounded drug.

E. A pharmacy permittee shall provide compounding facilities that conform with the standards in this subsection.
1. In addition to the minimum area requirements of R4-23-609, R4-23-655, or R4-23-673, the compounding area:
   a. Complies with the requirements in R4-23-604(C)(1) and R4-23-611; and
   b. Has sufficient space to permit efficient pharmacy practice, free movement of personnel, and visual surveillance by a pharmacist.
2. If sterile pharmaceutical or radiopharmaceutical compounding is performed, provide a separate compounding area that complies with the rules governing sterile pharmaceuticals and radiopharmaceuticals.
3. A clean, dry, and temperature-controlled area and, if required, a refrigerated area, in which to store properly labeled containers of bulk drugs, chemicals, and materials used in compounding, that complies with state statutes and rules.

F. To protect drug product safety, identity, strength, quality, and purity, a pharmacy permittee shall ensure that equipment and utensils used in drug compounding conform with the standards in this subsection:

1. Are of appropriate design, adequate size, and suitably located for proper operation, cleaning, and maintenance;
2. Are made of material that is not reactive, additive, or absorptive when exposed to components, in-process materials, or drug products;
3. Are cleaned and sanitized before use;
4. If previously cleaned:
   a. Are protected from contamination before use; and
   b. Are inspected and determined suitable for use, by a pharmacist, immediately before initiation of compounding operations;
5. Are routinely inspected, calibrated, or checked to make proper performance certain.

G. A pharmacy permittee shall ensure that the pharmacist-in-charge establishes and implements procedures to prevent cross-contamination when drug products that require special precautions to prevent cross-contamination, such as penicillin, are used in a compounding procedure. The procedures shall include either the dedication of equipment or the meticulous cleaning of contaminated equipment before its use in compounding other drugs.

H. A pharmacy permittee shall ensure that the pharmacist-in-charge establishes and implements control procedures for components and drug product containers and closures, either written or electronically stored with printable documentation, that conform with the standards in this subsection.

1. Components and drug product containers and closures are:
   a. Stored off the floor,
   b. Handled and stored to prevent contamination, and
   c. Rotated so the oldest approved stock is used first.
2. Container closure systems comply with official compendium standards.
3. Drug product containers and closures are clean and made of material that is not reactive, additive, or absorptive.
4. Drug product containers and closures used for compounded sterile pharmaceuticals and radiopharmaceuticals are handled, sterilized, and stored in compliance with R4-23-670, R4-23-681, and R4-23-682.

I. A pharmacy permittee shall ensure that the pharmacist-in-charge establishes and implements drug compounding controls that conform with the standards in this subsection.

1. Drug compounding procedures are available in either written form or electronically stored with printable documentation:
   a. To ensure that a finished drug product has the identity, strength, quality, and purity it is purported or represented to possess, the procedures include, for each drug compounded, a description of;
      i. The components, their amounts, the order of component addition, and the compounding process;
      ii. The required equipment and utensils; and
      iii. The drug product container and closure system proper for the sterility and stability of the drug as it is intended to be used.
   b. To test the product being compounded, the procedures monitor the output and validate the performance of compounding processes that may cause variability in the final drug product, including assessing:
      i. Dosage form weight variation;
      ii. Adequacy of mixing to ensure uniformity and homogeneity; and
      iii. Clarity, completeness, or pH of solutions.
2. Components for drug compounding are accurately weighed, measured, or subdivided. To ensure that each weight, measure, or subdivision is correct as stated in the compounding procedures, a pharmacist checks and rechecks, or assumes responsibility for checking and rechecking, the operations at each stage of the compounding process.
3. When a component is removed from its original container and transferred to another container, the new container label contains, in full text or an abbreviated code system, the following:
   a. The component name,
   b. The lot or control number,
   c. The weight or measure,
   d. The beyond-use date, and
   e. The transfer date.

J. A pharmacy permittee shall ensure that the pharmacist-in-charge stores any quantity of compounded drug produced in excess of the quantity dispensed in accordance with subsection (B).

1. In an appropriate container with a label that contains:
   a. A complete list of components or the drug product name;
   b. The preparation date;
   c. The assigned lot or control number; and
   d. A beyond-use date based upon the pharmacist's professional judgment, but not more than the maximum guidelines recommended in the Pharmacy Compounding Practices chapter of the official compendium unless there are published data based on testing that show a longer period is appropriate; and
2. Under conditions, dictated by the drug's composition and stability characteristics, that ensure its strength, quality, and purity.

K. A pharmacy permittee shall ensure that the pharmacist-in-charge establishes and implements recordkeeping procedures that comply with this subsection:

1. Drug compounding procedures and other records required by this Section are retained in the pharmacy for not less than three years; and
2. Drug compounding procedures and other records required by this Section are readily available for inspection by the Board or its designee.

Historical Note

Adopted effective August 5, 1997 (Supp. 97-3).

R4-23-411. Reserved

R4-23-412. Reserved

R4-23-413. Reserved

R4-23-414. Reserved

R4-23-415. Impaired Licensees - Treatment and Rehabilitation

A. The Board may contract with qualified organizations to operate a program for the treatment and rehabilitation of pharmacists and interns impaired as the result of alcohol or other drug abuse, pursuant to A.R.S. § 32-1932.01.

B. Participants in the program are either "confidential" or "known." Confidential participants are self-referred and may remain unidentified to the Board, subject to maintaining compliance with their program contract. Known participants are under Board order to complete a minimum tenure in the program. After a known participant completes the minimum tenure, the Board may terminate the Board order and reinstate the participant's license to practice pharmacy.

C. The program contract with a qualified organization shall include as a minimum the following:
1. Duties and responsibilities of each party.
2. Duration, not to exceed two years, of contract and terms of compensation.
3. Quarterly reports from the program administrator to the Board indicating:
   a. Identity of participants;
      i. By name, if a known participant; or
      ii. By case number, if a confidential participant;
   b. Status of each participant, including;
      i. Clinical findings;
      ii. Diagnosis and treatment recommendations;
      iii. Program activities; and
      iv. General recovery and rehabilitation program information.
4. The program administrator shall report immediately to the Board the name of any impaired pharmacist or pharmacy intern who poses a danger to the public or himself.
5. The program administrator shall report to the Board, as soon as possible, the name of any impaired pharmacist or pharmacy intern:
   a. Who refuses to submit to treatment;
   b. Whose impairment is not substantially alleviated through treatment; or
   c. Who violates the terms of their contract.
6. The program administrator shall periodically provide informational programs to the profession, including approved continuing education programs on the topic of drug and chemical impairment, treatment, and rehabilitation.

D. Pursuant to A.R.S. § 32-1903(F), the Board may publish the names of participants under current Board orders.

E. A majority of the Board may request the treatment records for any participant. The program administrator shall provide treatment records within 10 working days of receiving a written request from the Board for such records. Upon request of the program administrator or the Board, a program participant shall authorize a drug and alcohol treatment facility or program or a private practitioner or treatment program to release the participant's records to the program administrator or the Board.

F. On the recommendation of the program administrator or a Board member and by mutual consent, the program administrator, Board member, Board staff, and program participant may meet informally to discuss program compliance.

Historical Note
New Section adopted by final rulemaking at 6 A.A.R. 467, effective January 4, 2000 (Supp. 00-1).

R4-23-416. Reserved

R4-23-417. Reserved

R4-23-418. Reserved

R4-23-419. Reserved

R4-23-420. Reserved

R4-23-421. Drug Therapy Management

A. A pharmacist qualified under R4-23-424 may provide drug therapy management under A.R.S. § 32-1970 after a physician's initial diagnosis of a patient if drug therapy management:
1. Is guided by a Board-approved drug therapy management agreement; and
2. Occurs in one of the following pharmacy practice sites:
   a. An acute care hospital,
   b. A nursing care institution,
   c. A staff model HMO, or
   d. A community health center as defined in A.R.S. § 32-1921 and A.R.S. § 36-2907.06.

B. A drug therapy management agreement shall contain the following:
1. The criteria and medical conditions under which the pharmacist may modify a patient's drug therapy;
2. The specific modifications of drug therapy that the pharmacist may make including drug, dose, and dosage form;
3. The criteria and medical conditions under which the pharmacist may implement a patient's drug therapy;
4. The specific drug therapy that a pharmacist may implement including drug, dose, and dosage form;
5. The subjective and objective patient assessment parameters that a pharmacist uses to evaluate a patient's drug therapy at each patient visit, including ordering and interpreting a patient's laboratory tests;
6. The subjective and objective patient assessment criteria that indicate when a pharmacist shall consult with a supervisory physician or if unavailable, an alternate physician, including the timing and nature of a consultation with or referral to a supervisory or alternate physician and the specific procedures for a consultation with or referral to a supervisory or alternate physician;
7. The content and frequency of the periodic status report on a patient that a pharmacist shall provide in writing to or in a meeting with the supervisory physician;
8. The procedure for terminating the drug therapy management agreement;
9. The names of the supervisory physician, the alternate physician, and the pharmacist authorized to provide services under the agreement; and
10. The signature of all persons named in subsection (B)(9).

Historical Note
New Section made by final rulemaking at 8 A.A.R. 4052, effective November 9, 2002 (Supp. 02-3).

R4-23-422. Drug Therapy Management - Duties of the Board

A. The Board shall:
1. Appoint a Drug Therapy Management Advisory Committee;
2. In consultation with Board staff and the Drug Therapy Management Advisory Committee, approve or deny an initial drug therapy management agreement and the annual renewal of an existing drug therapy management agreement;
3. Terminate a pharmacist's drug therapy management agreement if the pharmacist:
   a. Does not renew the agreement on or before the approval date anniversary; or
   b. Is found by the Board to lack the qualifications required in R4-23-424; and
4. In processing a drug therapy management agreement application, comply with the application process established in R4-23-602, except the substantive review time-frame is 180 days and the overall time-frame is 200 days.

B. The Board may terminate a pharmacist's drug therapy management agreement if the Board determines that the pharmacist is violating the requirements of the drug therapy management agreement or federal or state drug laws.

Historical Note
New Section made by final rulemaking at 8 A.A.R. 4052, effective November 9, 2002 (Supp. 02-3).

R4-23-423. Drug Therapy Management Advisory Committee

A. The Drug Therapy Management Advisory Committee shall:
1. Consist of an osteopathic physician, an allopathic physician, and two pharmacists with prior or current experience in drug therapy management;
2. Serve at the pleasure of the Board;
3. Serve for a term of two years unless removed or reappointed by the Board;
4. Review initial and renewal drug therapy management agreement applications; and
5. Advise the Board regarding the approval or denial of reviewed drug therapy management agreement applications.

B. The Drug Therapy Management Advisory Committee members are not eligible for compensation from the Board.

Historical Note

New Section made by final rulemaking at 8 A.A.R. 4052, effective November 9, 2002 (Supp. 02-3).

R4-23-424. Drug Therapy Management - Pharmacist and Physician Qualifications

A. Pharmacist qualifications.
1. Before initiating a drug therapy management agreement with a supervisory physician, a pharmacist shall have:
   a. A current, unrestricted license issued by the Board; and
   b. Proof of one of the following:
      i. Completion of a pharmacy practice residency accredited by the American Society of Health Systems Pharmacists or the American Pharmaceutical Association;
      ii. Current board specialty certification from the Board of Pharmaceutical Specialists or current certification as a Certified Geriatric Pharmacist;
      iii. A Doctor of Pharmacy degree and completion of an American Council on Pharmaceutical Education approved certificate program in each area of practice covered in the drug therapy management agreement; or
      iv. A Bachelor's degree in Pharmacy, satisfactory completion of an American Council on Pharmaceutical Education approved certificate program in each area of practice covered in the drug therapy management agreement, and appropriate credentialing issued by the governing body of a qualifying Arizona practice site described in A.R.S. § 32-1970.
2. To ensure that a pharmacist who provides drug therapy management is competent to continue providing the services delineated in a drug therapy management agreement, a pharmacist shall annually complete six contact hours (0.6 CEU's) of continuing education for each area of practice covered by the pharmacist's drug therapy management agreement. The continuing education hours may be used to satisfy the continuing education requirements for licensure as a pharmacist.

B. Supervisory physician qualifications. Before initiating a drug therapy management agreement with a pharmacist, a supervisory physician shall:
1. Have a current, unrestricted license from the Allopathic Board of Medical Examiners or the Board of Osteopathic Examiners in Medicine and Surgery; and
2. Not be a resident in a post-graduate medical training program.

C. Alternate physician qualifications. Before initiating a drug therapy management agreement with a pharmacist, an alternate physician shall:
1. Have a current, unrestricted license from the Allopathic Board of Medical Examiners or the Board of Osteopathic Examiners in Medicine and Surgery; and
2. Not be a resident in a post-graduate medical training program.

Historical Note

New Section made by final rulemaking at 8 A.A.R. 4052, effective November 9, 2002 (Supp. 02-3).

R4-23-425. Drug Therapy Management - Pharmacist Duties

A. To obtain initial approval for a drug therapy management agreement, a pharmacist shall submit a completed application, on a form furnished by the Board, that includes:
1. Pharmacist name and Arizona pharmacist license number;
2. Documentation of the pharmacist's qualifications as specified in R4-23-424;
3. Practice site name, address, mailing address if different, telephone number, and fax number;
4. Documentation of practice site qualification under A.R.S. § 32-1970;
5. Supervisory physician name, office address, mailing address if different, telephone number, and fax number;
6. Documentation of the supervisory physician's qualifications as specified in R4-23-424;
7. Alternate physician name, office address, mailing address if different, telephone number, and fax number;
8. Documentation of the alternate physician's qualifications as specified in R4-23-424;
9. Description of the pharmacist's practice area or areas for which approval is sought;
10. An original and 11 copies of the drug therapy management agreement covering each practice area for which Board approval is sought;
11. Dated and signed affirmation of the supervisory physician's acceptance of the responsibility for oversight of the pharmacist's drug therapy management;
12. Dated and signed affirmation of an alternate physician's acceptance of the responsibility for temporary oversight of the pharmacist's drug therapy management; and
13. Dated and signed affirmation of the pharmacist's acceptance of the responsibility to provide drug therapy management as described in the drug therapy management agreement.

B. To renew an existing drug therapy management agreement, a pharmacist shall submit a completed renewal application, on a form furnished by the Board, that includes, in addition to the requirements of subsection (A), the following:
1. Documentation that the supervisory physician, alternate physician, and participating pharmacist reviewed the protocols contained in the agreement;
2. Documentation that the participating pharmacist completed the continuing education requirements specified in R4-23-424; and
3. An original and 11 copies of the drug therapy management agreement covering each practice area for which renewal is sought, including highlighting any requested modifications to the agreement.

C. A pharmacist who participates in a Board-approved drug therapy management agreement shall:
1. Renew the agreement annually on or before the initial approval date anniversary;

2. Before submitting the application to renew the agreement, participate with the supervisory physician in reviewing the agreement;
3. Notify the Board within ten days of termination of the drug therapy management agreement;
4. During the first appointment with a patient under a Board-approved drug therapy management agreement:
   a. Verify that a copy of the drug therapy management agreement, which includes the signature of the supervisory physician, alternate physician, and pharmacist, is placed in the patient's medical record;
   b. Verify that a copy of the supervisory physician's written order, which authorizes the pharmacist to collaboratively manage the patient's drug therapy, is placed in the patient's medical record; and
   c. Verify that a copy of the patient's written consent, which shows that the patient understands the pharmacist's role in the patient's care, the nature of the relationship with the supervisory physician, and the procedure for revoking consent, is placed in the patient's medical record;
5. Ensure compliance with the documentation requirements of R4-23-427;
6. Ensure compliance with quality assurance program required in R4-23-428;
7. Ensure compliance with the privacy requirements of R4-23-429; and
8. Comply with the Board-approved drug therapy management agreement.

Historical Note

New Section made by final rulemaking at 8 A.A.R. 4052, effective November 9, 2002 (Supp. 02-3).

R4-23-426. Drug Therapy Management - Physician Duties

A. Before referring a patient to a pharmacist, a supervisory physician who participates in a Board-approved drug therapy management agreement shall:
1. Have a physician-patient relationship with the patient and make a diagnosis of the patient;
2. Review the approved drug therapy management agreement with the patient;
3. Obtain the patient's consent to participate in the drug therapy management agreement;
4. Document the patient's consent to participate in the drug therapy management agreement by obtaining the patient's dated and signed consent that states that the patient has read, understood, and agreed to participate in the drug therapy management agreement. The dated and signed consent shall be placed in the patient's medical records;
5. Authorize a specific pharmacist to collaboratively manage a patient's drug therapy by placing a written order in the patient's medical record; and
6. Place a copy of the approved drug therapy management agreement in the patient's medical record to provide notice to other health care providers of the drug therapy management.

B. Physician supervision. A supervisory physician who supervises a pharmacist under a Board-approved drug therapy management agreement shall:
1. Before submitting the application to renew the agreement and in consultation with the participating alternate physician and pharmacist, review and approve the drug therapy management agreement;
2. Review and initial the pharmacist's documented care for appropriateness of care and compliance with the drug therapy management agreement when the patient visits the supervisory physician for follow-up or any other services;
3. Routinely evaluate the patient care provided by the pharmacist as specified in the drug therapy management agreement; and
4. Ensure that the supervisory physician or the alternate physician is readily available to the pharmacist for consultation, assistance, and direction by direct telecommunication or physical presence at the practice site.

C. Alternate physician duties. An alternate physician who participates in a Board-approved drug therapy management agreement shall ensure that the alternate physician is available to:
1. Temporarily assume responsibility for supervision and evaluation of the drug therapy management performed by the pharmacist;
2. Provide consultation, assistance, and direction to the pharmacist when the supervisory physician is unavailable; and
3. Before submitting the application to renew the agreement, participate with the supervisory physician and pharmacist in reviewing the agreement.

Historical Note

New Section made by final rulemaking at 8 A.A.R. 4052, effective November 9, 2002 (Supp. 02-3).

R4-23-427. Drug Therapy Management - Documentation

Documenting pharmacist-provided drug therapy management. A pharmacist who participates in drug therapy management under a Board-approved drug therapy management agreement shall:
1. After each patient-pharmacist appointment, document the drug therapy management for the patient in the patient's medical record at the practice site, including patient data, assessment of patient status, and treatment plan;
2. Date and sign the documentation required in subsection (1) in a patient's medical record with the pharmacist's first and last name, title, and Arizona pharmacist license number;
3. Document a consultation with or referral to the supervisory physician or the alternate physician; and
4. Document a consultation with a supervisory or alternate physician that results in a pharmacist's need to generate the physician's verbal prescription order for a drug not included in the drug therapy management agreement. The documentation shall include:
   a. The phrase "verbal order by Dr." and the name of the supervisory physician or alternate physician authorizing the verbal prescription order,
   b. The date and signature of the pharmacist generating the verbal prescription order in the same manner described in subsection (2), and
   c. The countersignature of the supervisory physician or alternate physician authorizing the verbal prescription order within 72 hours of the pharmacist-generated verbal prescription order.

Historical Note

New Section made by final rulemaking at 8 A.A.R. 4052, effective November 9, 2002 (Supp. 02-3).

R4-23-428. Drug Therapy Management - Quality Assurance

A. A pharmacist who provides drug therapy management shall, in cooperation with the supervisory physician and the appropriate committee of the practice site, develop and implement a continuous quality assurance and improvement program that includes standards and procedures to identify, evaluate, and improve the quality of pharmacist-provided drug therapy management.

B. Periodic status reports or meetings between a pharmacist and supervisory physician regarding care of a patient under the drug therapy management agreement shall include evaluating and documenting patient status and the quality of care provided by the pharmacist.

Historical Note

New Section made by final rulemaking at 8 A.A.R. 4052, effective November 9, 2002 (Supp. 02-3).

R4-23-429. Drug Therapy Management - Privacy

A. A pharmacist who provides drug therapy management shall perform drug therapy management activities in a private and distinct area of the practice site.

B. In a practice site where a pharmacist provides drug therapy management under a drug therapy management agreement, a pharmacy permittee shall ensure that a private and distinct area of similar size and environment to that used by other primary care providers at the practice site is available for the performance of pharmacist-provided drug therapy management activities.

Historical Note

New Section made by final rulemaking at 8 A.A.R. 4052, effective November 9, 2002 (Supp. 02-3).

ARTICLE 5. RECODIFIED

Article 5, consisting of Sections R4-23-501 and R4-23-502, recodified to Article 8 at 9 A.A.R. 4011, effective August 18, 2003 (Supp. 03-3).

R4-23-501. Recodified

Historical Note

Former Rule 5.2110; Amended effective August 9, 1983 (Supp. 83-4). Amended by final rulemaking at 8 A.A.R. 4898, effective January 5, 2003 (Supp. 02-4). Recodified to R4-23-801 at 9 A.A.R. 4011, effective August 18, 2003 (Supp. 03-3).

R4-23-502. Recodified

Historical Note

Former Rule 5.2510. Amended by final rulemaking at 8 A.A.R. 4898, effective January 5, 2003 (Supp. 02-4). Recodified to R4-23-802 at 9 A.A.R. 4011, effective August 18, 2003 (Supp. 03-3).

R4-23-503. Repealed

Historical Note

Former Rules 5.3500, 5.3520, 5.3540, 5.3550, 5.3560, 5.3570, 5.3580, 5.3590, 5.4110, and 5.6110; Repealed effective August 2, 1982 (Supp. 82-4).

R4-23-504. Repealed

Historical Note

Former Rule 5.7010; Amended effective August 10, 1978 (Supp. 78-4). Repealed effective August 2, 1982 (Supp. 82-4).

R4-23-505. Repealed

Historical Note

Former Rules 5.7100, 5.8100, 5.8500, 5.9100, and 5.9500; Amended effective August 10, 1978 (Supp. 78-4). Repealed effective August 2, 1982 (Supp. 82-4).

R4-23-506. Repealed

Historical Note

Adopted effective December 3, 1974 (Supp. 75-1). Repealed effective August 24, 1992 (Supp. 92-3).

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-601. General Provisions

A. Permit required to sell drugs. A person shall have a current Board permit to:
1. Sell a drug in Arizona, or
2. Sell a drug from outside Arizona and ship the drug into Arizona.

B. A medical practitioner is exempt from subsection (A) to administer a drug for the emergency needs of a patient.

C. Permit fee. Permits are issued biennially on an odd- and even-year expiration based on the assigned permit number. The fee, specified in R4-23-205, is not refundable under any circumstances except the Board's failure to comply with the permit time-frames established in R4-23-602.

D. Record of receipt and disposal of drugs.
1. Every person manufacturing a drug, including repackaging or relabeling, shall prepare and retain the manufacturing, repackaging, or relabeling date for each drug.
2. Every person receiving, selling, delivering, or disposing of a drug shall record and retain for not less than three years the following information:
   a. The name, strength, dosage form, and quantity of each drug received, sold, delivered, or disposed;
   b. The name, address, and license or permit number, if applicable, of the person from whom each drug is received;
   c. The name, address, and license or permit number, if applicable, of the person to whom each drug is sold or delivered, or of the person who disposes of each drug; and
   d. The date of each drug receipt, sale, deliver, or disposal.
3. The record required in this subsection shall be available for inspection by the Board or its compliance officer during regular business hours.
4. If the record required in this subsection is stored in a centralized recordkeeping system and not immediately available for inspection, a permittee, manager, or pharmacist-in-charge shall provide the record within four working days of the Board's or its compliance officer's request.

E. Fire- or water-damaged drugs or devices. No person shall expose, sell, or offer to sell any drug or device damaged by water, fire, or from human or animal consumption or use.

Historical Note

Former Rules 6.1100, 6.1200, 6.1300, 6.1400, and 6.1500. Amended effective August 10, 1978 (Supp. 78-4). Amended subsection (C) effective August 9, 1983 (Supp. 83-4). Amended subsection (C) effective August 12, 1988 (Supp. 88-3). Amended by final rulemaking at 6 A.A.R. 4656, effective November 14, 2000 (Supp. 00-4).

R4-23-602. Permit Application Process and Time-frames

A. A person applying for a permit shall submit to the Board Office an application packet consisting of:
1. A completed application form for the desired permit signed by the applicant;
2. A cashier's, certified, business, or personal check, or money order for the applicable biennial permit fee; and
3. Other information or documents required by R4-23-603, R4-23-604, R4-23-605, R4-23-606, R4-23-607, or R4-23-671.

B. The Board Office shall deem an application packet received on the date that the Board Office stamps on the packet immediately upon receipt.

C. The Board Office shall finish an administrative completeness review within 20 days from the date of receipt of an application packet.
1. The Board Office shall issue a written notice of administrative completeness to the applicant if no deficiencies are found in the application packet.
2. If the application packet is incomplete, the Board Office shall provide the applicant with a written notice that includes a comprehensive list of the missing information. The 20-day time-frame for the Board Office to finish the administrative completeness review is suspended from the date the notice of incompleteness is served until the applicant provides the Board Office with all missing information.
3. If the Board Office does not provide the applicant with notice regarding administrative completeness, the application packet shall be deemed complete 20 days after receipt by the Board Office.

D. An applicant with an incomplete application packet shall submit to the Board Office all of the missing information within 60 days of service of the notice of incompleteness.
1. If an applicant cannot submit all missing information within 60 days of service of the notice of incompleteness, the applicant may obtain an extension by submitting a written request to the Board Office postmarked or delivered within 60 days of service of the notice of incompleteness.
2. The written request for an extension shall document the reasons the applicant is unable to meet the 60-day deadline.
3. The Board Office shall review the request for an extension of the 60-day deadline and grant the request if the Board Office determines that an extension of the 60-day deadline will enable the applicant to assemble and submit the missing information. An extension of the 60-day deadline shall be for no more than 60 days. An applicant that requires an additional extension shall submit an additional written request in accordance with this subsection. The Board Office shall notify the applicant in writing of its decision to grant or deny the request for an extension.

E. If an applicant fails to submit a complete application packet within the time allowed, the Board Office shall close the applicant's file. An applicant whose file has been closed and who later wishes to obtain a permit shall apply again in accordance with subsection (A).

F. For a nonprescription drug permit applicant, the Board Office shall issue a permit on the day that the Board Office determines an administratively complete application packet is received.

G. Except as described in subsection (F), from the date on which the administrative completeness review of an application packet is finished, the Board Office shall complete a substantive review of the applicant's qualifications in no more than 120 days.
1. If an applicant is found to be ineligible, the Board Office shall issue a written notice of denial to the applicant;
2. If an applicant is found to be eligible, the Board Office shall recommend to the Board that the applicant be issued a permit. Upon receipt of the Board Office's recommendation, the Board shall either issue a permit to the applicant or if the Board determines the applicant does not meet eligibility requirements, return the matter to the Board Office.
3. If the Board Office finds deficiencies during the substantive review of the application packet, the Board Office shall issue a written request to the applicant for additional documentation.
4. The 120-day time-frame for a substantive review for the issuance or denial of a permit is suspended from the date of the written request for additional documentation until the date that all documentation is received.
5. When the applicant and the Board Office mutually agree in writing, the 120-day substantive review time-frame may be extended once for no more than 35 days.

H. For the purpose of A.R.S. § 41-1072 et seq., the Board establishes the following time-frames for permits.
1. Administrative completeness review time-frame: 20 days.
2. Substantive review time-frame:
   a. Nonprescription drug permit: none;
   b. Except as described in subsection (H)(2)(a): 120 days.
3. Overall time-frame:
   a. Nonprescription drug permit: 20 days;
   b. Except as described in subsection (H)(3)(a): 140 days.

Historical Note
Former Rules 6.2100, 6.2200, 6.2300, 6.2400, 6.2500, 6.2600, 6.2610, 6.2620, 6.2630, 6.2640, and 6.2650. Amended effective August 10, 1978 (Supp. 78-4). Amended effective August 9, 1983 (Supp. 83-4). Repealed effective August 12, 1988 (Supp. 88-3). New Section adopted effective August 5, 1997 (Supp. 97-3). Amended by final rulemaking at 6 A.A.R. 4589, effective November 14, 2000 (Supp. 00-4).

R4-23-603. Nonprescription Drugs, Retail

A. Permit. A person, including the following, shall not sell or distribute a nonprescription drug without a current Board-issued permit:
1. A grocer;
2. Other non-pharmacy retail outlet; or
3. Mobile or non-fixed location retailer, such as a swap-meet vendor.

B. A medical practitioner licensed under A.R.S. Title 32 is exempt from the requirements of subsection (A).

C. Application. To obtain a permit to sell a nonprescription drug, a person shall submit a completed application, on a form furnished by the Board, that includes:
1. Whether applying for Category I or Category II permit;
2. Business name, address, mailing address, if different, telephone number, and facsimile number;
3. Owner's name, if corporation or partnership, officers or partners, including address and title;
4. Date business started or planned opening date;
5. Documentation of compliance with local zoning laws;
6. Type of business, such as convenience, drug, grocery, or health food store, swap-meet vendor, or vending machine;
7. If application is submitted because of ownership change, former owner's name and business name, if different;
8. Date signed, applicant's verified signature; and
9. Fee specified in R4-23-205.

D. Drug sales: A nonprescription drug permittee:
1. Shall sell a drug only in the original container packaged and labeled by the manufacturer; and
2. Shall not package, repackage, label, or relabel any drug.

E. Inspection. A nonprescription drug permittee shall consent to inspection during business hours by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).

F. Quality control. A nonprescription drug permittee shall:
1. Ensure that all drugs stocked, sold, or offered for sale are:
   a. Kept clean;
   b. Protected from contamination, excessive heat, cold, sunlight, and other deteriorating factors; and
   c. Comply with federal law; and
2. Develop and implement a program to ensure that:
   a. Any expiration-dated drug is reviewed regularly;
   b. Any drug, that exceeds its expiration date, is deteriorated or damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and
   c. Any quarantined drug is destroyed or returned to its source of supply.

G. Nonprescription drug vending machine outlet. In addition to the requirements of R4-23-601, R4-23-602, and subsections (A) through (F), a person selling or distributing a nonprescription drug in a vending machine shall comply with the following requirements:
1. Each individual vending machine is considered an outlet and shall have a Board-issued nonprescription drug permit;
2. Each nonprescription-drug-permitted vending machine shall display in public view an identification seal, furnished by the Board, containing the permit number, vending machine's serial number, owner's name, telephone contact number, and permit expiration date;
3. Each nonprescription-drug-permitted vending machine is assigned a specific location that is within a weather-tight structure, protected from direct sunlight, and maintained at a temperature not less than 59° F and not greater than 86° F;
4. Each nonprescription drug sold in a vending machine is packaged and labeled in the manufacturer's original FDA-approved container;
5. A nonprescription-drug-permitted vending machine is subject to inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4) as follows:
   a. The owner, manager, or other staff of the nonprescription drug permittee shall provide access to the contents of the vending machine within 24 hours of a request from a Board compliance officer or other authorized officer of the law; or
   b. The Board compliance staff shall have independent access to the vending machine;
6. Before relocating or retiring a nonprescription-drug-permitted vending machine, the owner or manager shall notify the Board in writing. The notice shall include:
   a. Permit number;
   b. Vending machine's serial number;
   c. Action planned (relocate or retire); and
   d. If retiring a vending machine, the disposition of the nonprescription drug contents of the vending machine;
7. The sale or distribution of a precursor chemical or regulated chemical in a vending machine is prohibited unless the nonprescription drug permittee provides written proof to the Board of compliance with the requirements of A.R.S. §§ 13-3401, 13-3404, and 13-3404.01; and
8. Under no circumstance may expired drugs be sold or distributed for human or animal consumption.

Historical Note

Adopted effective August 10, 1978 (Supp. 78-4).
Amended subsection (D) paragraph (1) and added subsection (G) effective April 20, 1982 (Supp. 82-2).
Amended effective August 12, 1988 (Supp. 88-3).
Amended effective February 8, 1991 (Supp. 91-1).
Amended effective August 5, 1997 (Supp. 97-3).
Amended by final rulemaking at 6 A.A.R. 4589, effective November 14, 2000 (Supp. 00-4).

R4-23-604. Resident Drug Manufacturer

A. Permit. A person shall not manufacture, package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical without a current Board-issued drug manufacturer permit.

B. Application. To obtain a permit to operate a drug manufacturing firm in Arizona, a person shall submit a completed application, on a form furnished by the Board, that includes:
1. Business name, address, mailing address, if different, telephone number, and facsimile number;
2. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
3. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
4. Whether the owner, any officer, or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
5. Whether the owner, any officer, or active partner has ever been denied a drug manufacturer permit in this state or any other jurisdiction, and if so, indicate where and when;
6. A copy of the drug list required by the FDA;
7. Plans or construction drawings showing facility size and security for the proposed business;
8. Applicant's and manager's name, address, emergency telephone number, and resume indicating educational or experiential qualifications related to drug manufacturer operation;
9. Pharmacist-in-charge's name, address, emergency telephone number, Arizona pharmacist license number, and expiration date;
10. The applicant's current FDA drug manufacturer or repackager registration number and expiration date;
11. Documentation of compliance with local zoning laws;
12. For an application submitted because of ownership change, the former owner's name and business name, if different;
13. Date signed, applicant's, corporate officer's, partner's, manager's, or pharmacist-in-charge's verified signature and title, and
14. Fee specified in R4-23-205.

C. Before issuing a drug manufacturer permit, the Board shall:
1. Receive and approve a completed permit application;
2. Interview the applicant and manager, if different from the applicant, and the pharmacist-in-charge at a Board meeting; and
3. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.

D. Notification. A drug manufacturer permittee shall notify the Board of changes involving the drug list, ownership, address, telephone number, name of business, manager, or pharmacist-in-charge, including manager's or pharmacist-in-charge's telephone number.

E. Manufacturing and distribution.
1. A drug manufacturer permittee shall manufacture and distribute a drug only:

a. To a pharmacy, drug manufacturer, and full-service or nonprescription drug wholesaler currently permitted by the Board;
b. To a medical practitioner currently licensed as a medical practitioner as defined in A.R.S. § 32-1901; or
c. To a properly permitted, registered, licensed, or certified person or firm of another jurisdiction; and
d. Under the supervision of an Arizona Board-licensed pharmacist as required in A.R.S. § 32-1961. Manufacturing processes that require the supervision of a pharmacist include weighing, mixing, compounding, tableting, packaging, and labeling.

2. Before manufacturing and distributing a drug that is not listed on a drug manufacturer's permit application, the drug manufacturer permittee shall send to the Board office a written request to amend the permit application, including documentation of FDA approval to manufacture the drug not listed on the original permit application. If a request to amend a permit application includes the documentation required in this subsection, the Board or its designee shall approve the request to amend within 30 days of receipt.

F. A drug manufacturer permit is subject to denial, suspension, probation, or revocation under A.R.S. § 32-1932.

G. A drug manufacturer permittee shall:

1. Designate an Arizona Board-licensed pharmacist as the pharmacist-in-charge. The pharmacist-in-charge shall:
   a. Communicate Board directives to the management, other pharmacists, interns, and other personnel of the drug manufacturer; and
   b. Ensure compliance with all federal and state drug laws and rules by the drug manufacturer; and
2. Ensure that an Arizona Board-licensed pharmacist is present at the facility whenever a drug is manufactured, packaged, repackaged, labeled, or relabeled.

H. Current Good Manufacturing Practice. A drug manufacturer permittee shall comply with the current good manufacturing practice requirements of 21 CFR 210 through 211, published April 1, 2000, and no future amendments or editions, incorporated by reference and on file with the Board and the Office of the Secretary of State.

I. Records. A drug manufacturer permittee shall:

1. Establish and implement written procedures for maintaining records pertaining to production, process control, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law;
2. Retain the records required by this Article and 21 CFR 210 through 211 as incorporated in subsection (H) for at least two years after distribution of a drug or one year after the expiration date of a drug, whichever is longer; and
3. Make the records required by this Article and 21 CFR 210 through 211 as incorporated in subsection (H) available within 48 hours for review by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).

J. Inspections. A drug manufacturer permittee shall make the drug manufacturer's facility available for inspection by the Board or its compliance officer under A.R.S. § 32-1904.

K. Nonresident drug manufacturer. A nonresident drug manufacturer shall comply with the requirements of R4-23-607.

L. Manufacturing radiopharmaceuticals. Before manufacturing a radiopharmaceutical, a drug manufacturer permittee shall:

1. Comply with the regulatory requirements of the Arizona Radiation Regulatory Agency, the U.S. Nuclear Regulatory Commission, the FDA, and this Section;
2. Be or employ an Arizona Board-licensed authorized nuclear pharmacist as specified in R4-23-681(A);
3. Comply with the requirements specified in R4-23-682(F)(1), (2), (3), and (5);
4. Hold a current Arizona Radiation Regulatory Agency Radioactive Materials License. If a drug manufacturer permittee who manufactures radiopharmaceuticals fails to maintain a current Arizona Radiation Regulatory Agency Radioactive Materials License, the permittee's drug manufacturer permit shall be immediately suspended pending a hearing by the Board;
5. Designate an authorized nuclear pharmacist as the pharmacist-in-charge. The pharmacist-in-charge shall:
   a. Communicate Board directives to the management, other pharmacists, interns, and other personnel of the drug manufacturer; and
   b. Ensure compliance with all federal and state drug laws and rules by the drug manufacturer;
6. Ensure that an authorized nuclear pharmacist:
   a. Directly supervises all personnel who perform tasks in the manufacture and distribution of radiopharmaceuticals; and
   b. Is present at the facility whenever a radiopharmaceutical is manufactured, packaged, repackaged, labeled, relabeled, or distributed.

Historical Note

Former Rules 6.4001, 6.4002, 6.4003, 6.4004, 6.4005, 6.4006, 6.4007, 6.4008, 6.4009, 6.4100, 6.4110, 6.4111, 6.4115, 6.4116, 6.4120, 6.4122, 6.4190, 6.4191, 6.4200, 6.4250, 6.4300, 6.4350, 6.4355, 6.4360, 6.4400, 6.4401, 6.4403, 6.4410, 6.4430, 6.4450, 6.4500, 6.4510, 6.4530, 6.4533, 6.4600, 6.4610, 6.4640, 6.4660, 6.4700, 6.4710, and 6.4750. Adopted effective December 3, 1974 (Supp. 75-1). Amended effective August 10, 1978 (Supp. 78-4). Amended subsection (B) paragraph (2) effective April 20, 1982 (Supp. 82-2). Amended subsections (B), (G), (K) and (L) effective August 12, 1988 (Supp. 88-3). Amended effective August 24, 1992 (Supp. 92-3). Amended effective November 1, 1993 (Supp. 93-4). Amended by final rulemaking at 7 A.A.R. 3815, effective August 9, 2001 (Supp. 01-3).

R4-23-605. Resident Drug Wholesaler Permit

A. Permit. A person shall not operate a business or firm for the wholesale distribution of any drug, device, precursor chemical, or regulated chemical without a current Board-issued full-service or nonprescription drug wholesale permit.

B. Application.

1. To obtain a permit to operate a full-service or nonprescription drug wholesale firm in Arizona, a person shall submit a completed application on a form furnished by the Board that includes:
   a. The type of drug wholesale permit;
   b. Business name, address, mailing address, if different, telephone number, and facsimile number;
   c. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
   d. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;

e. Whether the owner, any officer or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
f. Whether the owner, any officer or active partner has ever been denied a drug wholesale permit in this state or any other jurisdiction, and if so, indicate where and when;
g. The type of drugs, nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
h. Plans or construction drawings showing facility size and security adequate for the proposed business;
i. Documentation of compliance with local zoning laws;
j. Manager's or responsible person's name, address, emergency telephone number, and resume indicating educational or experiential qualifications related to drug wholesale operation;
k. For an application submitted because of ownership change, the former owner's name and business name, if different;
l. Date signed, applicant's, corporate officer's, partner's, manager's, or responsible person's verified signature and title; and
m. Fee specified in R4-23-205.

2. Before issuing a full-service or nonprescription drug wholesale permit, the Board shall:
a. Receive and approve a completed permit application;
b. Interview the applicant and the responsible person, if different from the applicant, at a Board meeting; and
c. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.

C. Notification. A full-service or nonprescription drug wholesale permittee shall notify the Board of changes involving the type of drugs sold or distributed, ownership, address, telephone number, name of business, manager, or responsible person, including manager's or responsible person's telephone number.

D. Distribution restrictions.

1. Records.
a. A full-service drug wholesale permittee shall:
i. Maintain records to ensure full accountability of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical including dates of receipt and sales, names, addresses, and DEA registration numbers, if required, of suppliers or sources of merchandise, and customer names, addresses, and DEA registration numbers, if required;
ii. File the records required in subsection (D)(1)(a)(i) in a readily retrievable manner for a minimum of two years; and
iii. Make the records required in subsection (D)(1)(a)(i) available upon request during regular business hours for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4). Records kept at a central location apart from the business location and not electronically retrievable shall be made available within two business days.
b. A nonprescription drug wholesale permittee shall:
i. Maintain records to ensure full accountability of any, nonprescription drug, precursor chemical, or regulated chemical including dates of receipt and sales, names, addresses, and DEA registration numbers, if required, of suppliers or sources of merchandise, and customer names, addresses, and DEA registration numbers, if required;
ii. File the records required in subsection (D)(1)(b)(i) in a readily retrievable manner for a minimum of two years; and
iii. Make the records required in subsection (D)(1)(b)(i) available upon request during regular business hours for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4). Records kept at a central location apart from the business location and not electronically retrievable shall be made available within two business days.

2. Drug sales.
a. A full-service drug wholesale permittee shall:
i. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, or prescription-only drug or device, to anyone except a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
ii. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
iii. Maintain a copy of the current permit or license of each person or firm who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
iv. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
b. A nonprescription drug wholesale permittee shall:
i. Not sell or distribute, any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
ii. Maintain a record of the current permit or license of each person or firm who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and
iii. Provide permit and license records upon request of a Board compliance officer or other

authorized officer of the law as defined in A.R.S. § 32-1901(4).

c. Nothing in this subsection shall be construed to prevent the return of a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical to the original source of supply.

3. Out-of-state drug sales.
   a. A full-service drug wholesale permittee shall:
      i. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, to anyone except a properly permitted, registered, licensed, or certified person or firm of other jurisdictions;
      ii. Maintain a copy of the current permit, registration, license, or certificate of each person or firm who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
      iii. Provide permit, registration, license, and certificate records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4); and
   b. A nonprescription drug wholesale permittee shall:
      i. Not sell or distribute, any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a properly permitted, registered, licensed, or certified person or firm of another jurisdiction;
      ii. Maintain a record of the current permit, registration, license, or certificate of each person or firm who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and
      iii. Provide permit, registration, license, or certificate records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
4. Cash-and-carry sales.
   a. A full-service drug wholesale permittee shall complete a cash-and-carry sale or distribution of, any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, only after:
      i. Verifying the validity of the order; and
      ii. Verifying the identity of the pick-up person, for each transaction by confirming that the person or firm represented placed the cash-and-carry order; and
   b. A nonprescription drug wholesale permittee shall complete a cash-and-carry sale or distribution of, any nonprescription drug, precursor chemical, or regulated chemical, only after:
      i. Verifying the validity of the order; and
      ii. Verifying the identity of the pick-up person, for each transaction by confirming that the person or firm represented placed the cash-and-carry order.

E. Facility. A full-service or nonprescription drug wholesale permittee shall:

1. Ensure that the facility occupied by a full-service or nonprescription drug wholesale permittee is of adequate size and construction, well-lighted inside and outside, adequately ventilated, and kept clean, uncluttered, and sanitary;
2. Ensure that the warehouse facility:
   a. Is secure from unauthorized entry and
   b. Has an operational security system designed to provide protection against theft and diversion;
3. In a full-service drug wholesale facility, ensure that only authorized personnel may enter areas where any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is kept;
4. In a nonprescription drug wholesale facility, ensure that only authorized personnel may enter areas where any nonprescription drug, precursor chemical, or regulated chemical is kept;
5. In a full-service drug wholesale facility, ensure that any thermolabile narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is stored in an area where room temperature is maintained in compliance with storage conditions prescribed on the product label;
6. In a nonprescription drug wholesale facility, ensure that any thermolabile nonprescription drug, precursor chemical, or regulated chemical is stored in an area where room temperature is maintained in compliance with storage conditions prescribed on the product label;
7. Make the facility available for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4) during regular business hours;
8. In a full-service drug wholesale facility, provide a quarantine area for storage of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, misbranded, adulterated, or that is in an open container; and
9. In a nonprescription drug wholesale facility, provide a quarantine area for storage of any nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, misbranded, adulterated, or that is in an open container.

F. Quality controls.

1. A full-service drug wholesale permittee shall:
   a. Ensure that any fire, flood, or otherwise damaged or deteriorated narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is not sold, distributed, or delivered to any person for human or animal consumption;
   b. Ensure that a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is not manufactured, packaged, repackaged, labeled, or relabeled by any of its employees;
   c. Ensure that any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical stocked, sold, offered for sale, or delivered is:
      i. Kept clean;
      ii. Protected from contamination and other deteriorating environmental factors; and
      iii. In compliance with applicable federal and state law and official compendium storage requirements;

d. Maintain manual or automatic temperature and humidity recording devices or logs to document conditions in areas where any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is stored; and

e. Develop and implement a program to ensure that:

i. Any expiration-dated narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is reviewed regularly;

ii. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, that has less than 120 days remaining on the expiration date, is deteriorated, damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and

iii. Any quarantined narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to its source of supply.

2. A nonprescription drug wholesale permittee shall:

a. Ensure that any fire, flood, or otherwise damaged or deteriorated nonprescription drug, precursor chemical, or regulated chemical is not sold, distributed, or delivered to any person for human or animal consumption;

b. Ensure that a nonprescription drug, precursor chemical, or regulated chemical is not manufactured, packaged, repackaged, labeled, or relabeled by any of its employees;

c. Ensure that any nonprescription drug, precursor chemical, or regulated chemical stocked, sold, offered for sale, or delivered is:

i. Kept clean;

ii. Protected from contamination and other deteriorating environmental factors; and

iii. In compliance with applicable federal and state law and official compendium storage requirements;

d. Maintain manual or automatic temperature and humidity recording devices or logs to document conditions in areas where any nonprescription drug, precursor chemical, or regulated chemical is stored; and

e. Develop and implement a program to ensure that:

i. Any expiration-dated nonprescription drug, precursor chemical, or regulated chemical is reviewed regularly;

ii. Any nonprescription drug, precursor chemical, or regulated chemical, that has less than 120 days remaining on the expiration date, is deteriorated, damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and

iii. Any quarantined nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to its source of supply.

Historical Note

Former Rules 6.5110, 6.5120, 6.5130, 6.5140, 6.5210, 6.5220, 6.5230, 6.5240, 6.5310, 6.5320, 6.5410, and 6.5420. Amended effective August 10, 1978 (Supp. 78-4). Amended effective April 20, 1982 (Supp. 82-2). Amended subsection (A) effective August 12, 1988 (Supp. 88-3). Amended effective February 8, 1991 (Supp. 91-1). Amended effective August 24, 1992 (Supp. 92-3). Amended by final rulemaking at 6 A.A.R. 4589, effective November 14, 2000 (Supp. 00-4). Amended by final rulemaking at 10 A.A.R. 232, effective March 6, 2004 (Supp. 04-1).

R4-23-606. Pharmacy Permit, Community, Hospital, and Limited Service

A. Permit. A person shall not operate a pharmacy in Arizona without a current Board-issued pharmacy permit.

B. Application.

1. To obtain a permit to operate a new pharmacy or change ownership, relocate, or remodel an existing pharmacy in Arizona, a person shall submit a completed application, on a form furnished by the Board, that includes:

a. The type of pharmacy;

b. Business name, address, mailing address, if different, telephone number, and facsimile number;

c. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;

d. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;

e. Whether the owner, any officer, or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;

f. Whether the owner, any officer, or active partner has ever been denied a pharmacy permit in this state or any other jurisdiction, and if so, indicate where and when;

g. Whether the owner, any officer, or partner is a medical practitioner;

h. Name and telephone number of individual to contact before opening;

i. If applying for a hospital pharmacy permit, the hospital's Department of Health Services license number, number of beds, and manager's or administrator's name;

j. Planned opening, change of ownership, relocation, or remodel date;

k. Plans or construction drawings showing pharmacy size and security for the proposed business;

l. Documentation of compliance with local zoning laws;

m. Lease agreement and a disclosure statement indicating whether a medical practitioner receives income from the lease;

n. Pharmacist-in-charge's name;

o. For an application submitted because of ownership change, the former pharmacy's name, address, owner's name, and permit number;

p. Date signed, applicant's, corporate officer's, partner's, manager's, administrator's, or pharmacist-in-charge's verified signature and title; and

q. Fee specified in R4-23-205.

2. Before issuing a pharmacy permit, the Board shall:

a. Receive and approve a completed permit application; and

b. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.

3. Before issuing a pharmacy permit, the Board may interview the applicant and the pharmacist-in-charge, if different from the applicant, at a Board meeting based on the need for additional information.

C. Notification. A pharmacy permittee shall notify the Board of changes involving the type of pharmacy operated, pharmacy area, ownership, address, telephone number, name of business, pharmacist-in-charge, or staff pharmacist.

D. If any nonprescription drugs are sold outside the pharmacy area when the pharmacy area is closed, the pharmacy permittee shall ensure that the business has a current, Board-issued nonprescription drug permit as required in Sections R4-23-602 and R4-23-603.

E. Change of ownership. Before any change of ownership occurs, a prospective owner shall submit the application packet described under subsection R4-23-606(B), except for changes of stock ownership of less than 30% of the voting stock of a corporation or an existing and continuing corporation that is actively traded on any securities market or over-the-counter market.

F. Before the relocation or remodel of an existing pharmacy, the pharmacy permittee shall submit the application packet described under subsection R4-23-606(B), except a fee is not required. The new or remodeled facility shall pass a final inspection by a Board compliance officer before operations begin.

G. A pharmacy permittee shall submit the application packet described under subsection R4-23-606(B) for any change of officers in a corporation, except a fee and final inspection are not required.

Historical Note

Former Rules 6.6010, 6.6020, 6.6030, 6.6040, 6.6050, 6.6060, 6.6071, 6.6072, 6.6073, 6.6074, 6.6075, and 6.6076. Amended effective August 10, 1978 (Supp. 78-4). Amended subsections (G) and (H) effective April 20, 1982 (Supp. 82-2). Amended subsection (L) effective July 2, 1982 (Supp. 82-4). Amended subsections (G) and (H) effective August 12, 1988 (Supp. 88-3). Amended effective November 1, 1993 (Supp. 93-4). Section heading amended effective April 5, 1996 (Supp. 96-2). Amended by final rulemaking at 7 A.A.R. 3825, effective August 9, 2001 (Supp. 01-3).

R4-23-607. Nonresident Permits

A. Permit. A person, who is not a resident of Arizona, shall not sell or distribute any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona without:
1. A current Board-issued nonresident pharmacy permit, nonresident manufacturer permit, nonresident full-service or nonprescription drug wholesale permit, or nonresident nonprescription drug permit; and
2. A current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides.

B. Application. To obtain a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesale, or nonprescription drug permit, a person shall submit a completed application, on a form furnished by the Board, that includes:
1. Business name, address, mailing address, if different, telephone number, and facsimile number;
2. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
3. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
4. Whether the owner, any officer, or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
5. A copy of the applicant's current equivalent license or permit, issued by the licensing authority in the jurisdiction where the person or firm resides and required by subsection (A)(2);
6. For an application submitted because of ownership change, the former owner's name and business name, if different;
7. Date signed, applicant's, corporate officer's, partner's, manager's, administrator's, pharmacist-in-charge's, or responsible person's verified signature and title, and
8. Fee specified in R4-23-205.

C. In addition to the requirements of subsection (B), the following information is required:
1. Nonresident pharmacy.
   a. The type of pharmacy;
   b. Whether the owner, any officer, or active partner has ever been denied a pharmacy permit in this state or any other jurisdiction, and if so, indicate where and when;
   c. If applying for a hospital pharmacy permit, the number of beds, manager's or administrator's name, and a copy of the hospital's current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides;
   d. Pharmacist-in-charge's name and telephone number; and
   e. For an application submitted because of ownership change, the former pharmacy's name, address, and permit number; and
2. Nonresident manufacturer.
   a. Whether the owner, any officer, or active partner has ever been denied a drug manufacturer permit in this state or any other jurisdiction, and if so, indicate where and when;
   b. A copy of the drug list required by the FDA;
   c. Manager's or responsible person's name, address, and emergency telephone number; and
   d. The firm's current FDA drug manufacturer or repackager registration number and expiration date; and
3. Nonresident full-service or nonprescription drug wholesaler.
   a. The type of drug wholesale permit;
   b. Whether the owner, any officer, or active partner has ever been denied a drug wholesale permit in this state or any other jurisdiction, and if so, indicate where and when;
   c. The types of drugs, nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
   d. Manager's or responsible person's name, address, emergency telephone number, and resume indicating educational or experiential qualifications related to drug wholesale operation; and
4. Nonresident nonprescription drug retailer.
   a. Whether applying for Category I or Category II permit;

b. Date business started or planned opening date; and
c. Type of business, such as convenience, drug, grocery, or health food store, swap-meet vendor, or vending machine.

D. Notification.
1. Nonresident pharmacy. A nonresident pharmacy permittee shall notify the Board of changes involving the type of pharmacy operated, ownership, address, telephone number, name of business, or pharmacist-in-charge.
2. Nonresident manufacturer. A nonresident manufacturer permittee shall notify the Board of changes involving listed drugs, ownership, address, telephone number, name of business, or manager, including manager's telephone number.
3. Nonresident drug wholesaler. A nonresident full-service or nonprescription drug wholesale permittee shall notify the Board of changes involving the types of drugs sold or distributed, ownership, address, telephone number, name of business, or manager, including manager's telephone number.
4. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall notify the Board of changes involving permit category, ownership, address, telephone number, name of business, or manager, including manager's telephone number.

E. Drug Sales.
1. Nonresident pharmacy. A nonresident pharmacy permittee shall:
   a. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except:
      i. A pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board;
      ii. A medical practitioner currently licensed under A.R.S. Title 32; or
      iii. An Arizona resident upon receipt of a valid prescription order for the resident;
   b. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except:
      i. A pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board;
      ii. A medical practitioner currently licensed under A.R.S. Title 32; or
      iii. An Arizona resident either upon receipt of a valid prescription order for the resident or in the original container packaged and labeled by the manufacturer;
   c. Except for a drug sale that results from the receipt and dispensing of a valid prescription order for an Arizona resident, maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
   d. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
2. Nonresident manufacturer. A nonresident manufacturer permittee shall:
   a. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except, a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
   b. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
   c. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
   d. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
3. Nonresident full-service drug wholesaler. A nonresident full-service drug wholesale permittee shall:
   a. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
   b. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
   c. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
   d. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
4. Nonresident nonprescription drug wholesaler. A nonresident nonprescription drug wholesale permittee shall:
   a. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
   b. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and

c. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).

5. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall not:
   a. Sell, distribute, give away, or dispose of, a nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona except in the original container packaged and labeled by the manufacturer;
   b. Package, repackage, label, or relabel any drug, precursor chemical, or regulated chemical; or
   c. Sell, distribute, give away, or dispose of, any drug, precursor chemical, or regulated chemical to anyone in Arizona that exceeds its expiration date, is contaminated or deteriorated from excessive heat, cold, sunlight, moisture, or other factors, or does not comply with federal law.

F. When selling or distributing any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona, a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesale, or nonprescription drug permittee shall comply with federal law, the permittee's resident state drug law, and this Section.

Historical Note

Former Rules 6.6110, 6.6120, and 6.6130; Amended effective August 10, 1978 (Supp. 78-4). Repealed effective July 24, 1985 (Supp. 85-4). New Section adopted by final rulemaking at 6 A.A.R. 4589, effective November 14, 2000 (Supp. 00-4). Amended by final rulemaking at 7 A.A.R. 3825, effective August 9, 2001 (Supp. 01-3). Amended by final rulemaking at 10 A.A.R. 232, effective March 6, 2004 (Supp. 04-1).

R4-23-608. Change of Personnel and Responsibility

A. A community, hospital, or limited-service pharmacy permittee shall give the Board:
1. Notice by mail, facsimile, or electronic mail within ten days of employing or terminating a pharmacist; and
2. Immediate notice of designating or terminating a pharmacist-in-charge.

B. Responsibility of ownership and management. The owner and management of a pharmacy shall:
1. Ensure that pharmacists, interns, and other pharmacy employees comply with state and federal laws and administrative rules; and
2. Not overrule a pharmacist in matters of pharmacy ethics and interpreting laws pertaining to the practice of pharmacy or the distribution of drugs and devices.

C. The Board may suspend or revoke a pharmacy permit if the owner or management of a pharmacy violates subsection (B).

Historical Note

Former Rules 6.6140 and 6.6150; Amended subsection (A) effective August 9, 1983 (Supp. 83-4). Amended effective November 1, 1993 (Supp. 93-4). Amended by final rulemaking at 7 A.A.R. 4253, effective September 11, 2001 (Supp. 01-3).

R4-23-609. Pharmacy Area of Community Pharmacy

A. Minimum area of community pharmacy. The minimum area of a community pharmacy, the actual area primarily devoted to stocking drugs restricted to pharmacists, and to the compounding and dispensing of prescription medication, exclusive of office area or other support function area, shall not be less than 300 square feet. A maximum of three pharmacy personnel may practice or work simultaneously in the minimum area. The pharmacy permittee shall provide an additional 60 square feet of floor area for each additional pharmacist, graduate intern, pharmacy intern, pharmacy technician, pharmacy technician trainee, or support personnel who may practice or work simultaneously. All of the allotted square footage area, including adequate shelving, shall lend itself to efficient pharmaceutical practice and permit free movement and visual surveillance of personnel by the pharmacist.

B. Compounding and dispensing counter. On or after January 6, 2004, a pharmacy permit applicant or remodel or relocation applicant shall provide a compounding and dispensing counter that provides a minimum of three square feet of pharmacy counter working area of not less than 16 inches in depth and 24 inches in length for the practice of one pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee. For each additional pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee practicing simultaneously, there shall be an additional three square feet of pharmacy counter working area of not less than 16 inches in depth and 24 inches in length. The Board shall determine a pharmacy's total required compounding and dispensing counter area by multiplying the maximum number of personnel allowed in the pharmacy area using the requirements specified in subsection (A) by three square feet per person. A pharmacy permittee or pharmacist-in-charge may operate the pharmacy with a total pharmacy counter working area specified in subsection (A) that is equal to the actual maximum number of pharmacists, graduate interns, pharmacy interns, pharmacy technicians, and pharmacy technician trainees, working simultaneously in the pharmacy area times three square feet per person.

C. Working area for compounding and dispensing counter. The aisle floor area used by the pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee at the compounding and dispensing counter shall extend the full length of the counter and be clear and continuous for a minimum of 36 inches from any counter, fixture, or structure.

D. Area for patient counseling. On or after April 1, 1995, a pharmacy permit applicant or remodel or relocation applicant shall provide a separate and distinct patient counseling area that provides patient privacy. This subsection does not apply to a pharmacy exempt from the requirements of R4-23-402(B).

E. Narcotic cabinet or safe. To prevent diversion, narcotics and other controlled substances may be:
1. Kept in a separate locked cabinet or safe, or
2. Dispersed throughout the pharmacy's prescription-only drug stock.

F. Building security standard of community pharmacy area. The pharmacy area shall be enclosed by a permanent barrier or partition from floor or counter to structural ceiling or roof, with entry doors that can be securely locked. The barrier shall be designed so that only a pharmacist can access the area where prescription-only drugs, narcotics, and other controlled substances are stored, compounded and dispensed. The permanent barrier may be constructed of other than a solid material. If constructed of a material other than a solid, the openings or interstices of the material shall not be large enough to permit removal of items in the pharmacy area through the barrier. Any material used in the construction of the permanent barrier must be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The pharmacy permittee shall submit plans and specifications of the permanent barrier to the Board for approval.

G. Drug storage and security.

1. The pharmacy permittee shall ensure that drugs and devices are stored in a dry, well-lit, ventilated, and clean and orderly area. The pharmacy permittee shall maintain the drug storage area at temperatures that ensure the integrity of the drugs before dispensing as stated in the official compendium defined in A.R.S. § 32-1901(52) or the manufacturer's or distributor's labeling.
2. If the pharmacy permittee needs additional storage area for drugs that are restricted to sale by a pharmacist, the pharmacy permittee shall ensure that the area is contained by a permanent barrier from floor or counter to structural ceiling or roof. The pharmacy permittee shall lock all doors and gates to the drug storage area. Only a pharmacist with a key is permitted to enter the storage area, except in an extreme emergency.

H. A pharmacy permittee or pharmacist-in-charge shall ensure that the pharmacy working counter area is protected from unauthorized access while the pharmacy is open for business by a barrier not less than 66 inches in height or another method approved by the Board or its designee.

Historical Note

Former Rules 6.6210, 6.6220, 6.6230, 6.6240, 6.6250, 6.6310, 6.6320, and 6.6330; Amended effective August 10, 1978 (Supp. 78-4). Amended effective August 9, 1983 (Supp. 83-4). Amended effective November 1, 1993 (Supp. 93-4). Amended effective April 1, 1995; filed with the Secretary of State January 31, 1995 (Supp. 95-1). Amended by final rulemaking at 9 A.A.C. 5030, effective January 3, 2004 (Supp. 03-4).

R4-23-610. Community Pharmacy Personnel and Security Procedures

A. Every pharmacy shall have a pharmacist designated as the "pharmacist-in-charge."
1. The pharmacist-in-charge shall ensure the communication and compliance of Board directives to the management, other pharmacists, interns, and technicians of the pharmacy.
2. The pharmacist-in-charge shall:
   a. Conduct a biennial review and revision of all pharmacy policies and procedures, and
   b. Make all pharmacy policies and procedures available in the pharmacy for employee reference and inspection by the Board or its designee.
3. The pharmacist-in-charge shall ensure that the ratio of technicians to pharmacists working in the pharmacy does not exceed the ratio in R4-23-403(C).

B. Personnel permitted in the pharmacy area of a community pharmacy include pharmacists, graduate interns, pharmacy interns, compliance officers, drug inspectors, peace officers acting in their official capacity, pharmacy technicians, certified pharmacy technicians, support personnel, and other designated personnel. Pharmacy interns, graduate interns, pharmacy technicians, certified pharmacy technicians, support personnel, and other designated personnel shall be permitted in the pharmacy area only when a pharmacist is on duty, except in an extreme emergency.
1. The pharmacist-in-charge shall comply with the minimum area requirements as described in R4-23-609 for a community pharmacy and for compounding and dispensing counter area.
2. A pharmacist employed by a pharmacy shall ensure that the pharmacy is physically and electronically secure while the pharmacist is on duty.

C. In a community pharmacy, the pharmacy area, and any additional storage area for drugs that is restricted to access only by a pharmacist, except in an extreme emergency, shall be locked when a pharmacist is not present.

D. A pharmacist shall be the only person permitted to unlock the pharmacy area or any additional storage area for drugs restricted to access only by a pharmacist, except in an extreme emergency.

E. Prescription-only drugs and controlled substances received in an area outside the pharmacy area shall be immediately transferred unopened to the pharmacy area. Prescription-only drug and controlled substance shipments shall be opened and marked in the pharmacy area under the supervision of a pharmacist, graduate intern, or pharmacy intern.

F. A written prescription order or prescription medication container to be refilled may be left in the prescription area through a small opening or slot when the pharmacist is not present.

G. A pharmacist shall deliver prescription medication to the patient or secure prescription medication in the locked pharmacy when a pharmacist is not present. Prescription medication shall not be left outside the prescription area or picked up by the patient when the pharmacist is not present.

Historical Note

Former Rules 6.6410, 6.6420, 6.6430, 6.6440, 6.6450, 6.6460, 6.6470, 6.6480, and 6.6490; Amended subsection (F), deleted subsection (I) effective August 9, 1983 (Supp. 83-4). Amended effective May 16, 1990 (Supp. 90-2). Amended effective November 1, 1993 (Supp. 93-4). Amended effective April 1, 1995; filed with the Secretary of State January 31, 1995 (Supp. 95-1). Amended by final rulemaking at 5 A.A.R. 4441, effective November 2, 1999 (Supp. 99-4).

R4-23-611. Pharmacy Facilities

A. Facilities. A pharmacy permittee or pharmacist-in-charge shall ensure that:
1. A pharmacy's facilities are constructed according to state and local laws and ordinances;
2. A pharmacy facility's:
   a. Walls, ceilings, windows, floors, shelves, and equipment are clean and in good repair and order; and
   b. Counters, shelves, aisles, and open spaces are not cluttered;
3. Adequate trash receptacles are provided and emptied periodically during the day;
4. A pharmacy facility of any pharmacy permit issued or pharmacy remodeled after October 1, 2001 provides toilet facilities either:
   a. Within the pharmacy area, or
   b. No further than a walking distance of 50 feet from the pharmacy area;
5. The toilet facilities are maintained in a sanitary condition and in good repair;
6. All professional personnel and staff of the pharmacy keep themselves and their apparel clean while in the pharmacy area;
7. No animals, except guide dogs for the blind and guard dogs, are allowed in the pharmacy;
8. The pharmacy facility is kept free of insects and rodents; and
9. There is a sink with hot and cold running water, other than a sink in a toilet facility, within the pharmacy area for use in preparing drug products.

B. Supply of drugs and chemicals. A pharmacy permittee or pharmacist-in-charge shall ensure that:
1. A pharmacy maintains a stock of drugs and chemicals that:

a. Are sufficient to meet the normal demands of the trading area or patient base the pharmacy serves; and
b. Meet all standards of strength and purity as established by the official compendiums;

2. All stock, materials, drugs, and chemicals held for ultimate sale or supply to the consumer are not contaminated;
3. Policies and procedures are developed and implemented to prevent the sale or use of a drug or chemical:
   a. That exceeds its expiration date;
   b. That is deteriorated or damaged by reason of age, heat, light, cold, moisture, crystallization, chemical reaction, rupture of coating, disintegration, solidification, separation, discoloration, change of odor, precipitation, or other change as determined by organoleptic examination or by other means;
   c. That is improperly labeled;
   d. Whose container is defective; or
   e. That does not comply with federal law; and
4. The policies and procedures described in subsection (B)(3):
   a. Are made available in the pharmacy for employee reference and inspection by the Board or its designee; and
   b. Provide the following:
      i. Any expiration-dated drug or chemical is reviewed regularly;
      ii. Any drug or chemical that exceeds its expiration date, is deteriorated or damaged, improperly labeled, has a defective container, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and
      iii. Any quarantined drug or chemical is properly destroyed or returned to its source of supply.

Historical Note

Former Rules 6.6510, 6.6520, 6.6530, 6.6540, 6.6550, 6.6560, 6.6570, 6.6580, 6.6600, 6.6610, 6.6620, 6.6630, 6.6640, 6.6650, and 6.6660; Amended subsection (B) effective August 9, 1983 (Supp. 83-4). Amended effective April 1, 1995; filed with the Secretary of State January 31, 1995 (Supp. 95-1). Amended by final rulemaking at 7 A.A.R. 4253, effective September 11, 2001 (Supp. 01-3).

R4-23-612. Equipment

A pharmacy permittee or pharmacist-in-charge shall ensure that a pharmacy has the necessary equipment to allow a pharmacist to practice the profession of pharmacy, including the following:

1. Adequate refrigeration equipment dedicated to the storage of drugs and biologicals;
2. A C-V controlled substance register, if C-V controlled substances are sold without an order of a medical practitioner;
3. Graduates in assorted sizes;
4. One mortar and pestle;
5. Spatulas of assorted sizes including one nonmetallic;
6. Prescription balance, Class A with weights or an electronic balance of equal or greater accuracy;
7. One ointment tile or equivalent;
8. A current hard-copy or access to a current electronic-copy of the Arizona Pharmacy Act and administrative rules and Arizona Controlled Substance Act;
9. A professional reference library consisting of a minimum of one current reference or text, in hard-copy or electronic media, addressing the following subject areas:
   a. Pharmacology or toxicology,
   b. Therapeutics,
   c. Drug compatibility, and
   d. Drug product equivalency;
10. An assortment of labels, including prescription labels, transfer labels for controlled substances, and cautionary and warning labels;
11. A red C stamp as defined in R4-23-110, if C-III, C-IV, and C-V controlled substance invoices are not filed separately from other invoices;
12. Current antidote and drug interaction information; and
13. Regional poison control phone number prominently displayed in the pharmacy area.

Historical Note

Former Rule 6.6670; Former Section R4-23-612 repealed, new Section R4-23-612 adopted effective August 10, 1978 (Supp. 78-4). Amended effective August 9, 1983 (Supp. 83-4). Amended effective April 5, 1996 (Supp. 96-2). Amended by final rulemaking at 7 A.A.R. 4253, effective September 11, 2001 (Supp. 01-3).

R4-23-613. Procedure for Discontinuing a Pharmacy

A. A pharmacy permittee or pharmacist-in-charge shall provide written notice to the Board and the Drug Enforcement Administration (D.E.A.) at least 10 days before discontinuing operation of the pharmacy. The notice shall contain the following information:
   1. Name, address, pharmacy permit number, and D.E.A. registration number of the pharmacy discontinuing business;
   2. Name, address, pharmacy permit number (if applicable), and D.E.A. registration number of the licensee, permittee, or registrant to whom the prescription-only drugs and controlled substances will be sold or transferred;
   3. Name and address of the location where the discontinuing pharmacy's records of purchase and disbursement of controlled substances and prescription-only drugs will be kept and the person responsible for the records. These records shall be kept for a minimum of three years from the last transaction date.
   4. Name and address of the location where the discontinuing pharmacy's prescription files and patient profiles will be kept and the person responsible for the files and profiles. These records shall be kept for a minimum of three years from the date the last original or refill prescription was dispensed; and
   5. The proposed date of discontinuing business operations.

B. The pharmacy permittee shall ensure that all pharmacy signs and symbols are removed from both the inside and outside of the premises.

C. The pharmacy permittee or pharmacist-in-charge shall ensure that all state permits and certificates of registration are returned to the Board office and that D.E.A. registration certificates and unused D.E.A. Schedule II order forms are returned to the D.E.A. Regional Office in Phoenix.

D. The pharmacist-in-charge of the pharmacy discontinuing business shall ensure that:
   1. Only a pharmacist has access to the prescription-only drugs and controlled substances until they are transferred to the licensee, permittee, or registrant listed in subsection (A)(2);
   2. All prescription-only drugs and controlled substances are removed from the premises on or before the date the pharmacy is discontinued; and
   3. All controlled substances are transferred as follows:
      a. Take an inventory of all controlled substances that are transferred using the procedures in R4-23-1003;

b. Include a copy of the inventory with the controlled substances that are transferred;
c. Keep the original of the inventory with the discontinued pharmacy's records of drug purchase and disbursement for a minimum of three years from the date the pharmacy is discontinued;
d. Use a D.E.A. form 222 to transfer any Schedule II controlled substances; and
e. Transfer controlled substances that need destruction in the same manner as all other controlled substances.

E. Upon receipt of outdated or damaged controlled substances from a discontinued pharmacy, the licensee, permittee, or registrant described in subsection (A)(2) shall contact a D.E.A. registered reverse distributor for proper destruction of outdated or damaged controlled substances. If there are controlled substances a reverse distributor will not accept, the licensee, permittee, or registrant shall then contact the Board office and request an inspection for the purpose of drug destruction.

F. During the three year record retention period, the person described in subsection (A)(3) or (4) shall provide to the Board upon its request a discontinued pharmacy's records of the purchase and disbursement of controlled substances and prescription-only drugs, prescription files, and patient profiles.

Historical Note

New Section made by final rulemaking at 7 A.A.R. 3825, effective August 9, 2001 (Supp. 01-3).

R4-23-614. Reserved

R4-23-615. Reserved

R4-23-616. Reserved

R4-23-617. Reserved

R4-23-618. Reserved

R4-23-619. Reserved

R4-23-620. Reserved

R4-23-621. Reserved

R4-23-622. Reserved

R4-23-623. Reserved

R4-23-624. Reserved

R4-23-625. Reserved

R4-23-626. Reserved

R4-23-627. Reserved

R4-23-628. Reserved

R4-23-629. Reserved

R4-23-630. Reserved

R4-23-631. Reserved

R4-23-632. Reserved

R4-23-633. Reserved

R4-23-634. Reserved

R4-23-635. Reserved

R4-23-636. Reserved

R4-23-637. Reserved

R4-23-638. Reserved

R4-23-639. Reserved

R4-23-640. Reserved

R4-23-641. Reserved

R4-23-642. Reserved

R4-23-643. Reserved

R4-23-644. Reserved

R4-23-645. Reserved

R4-23-646. Reserved

R4-23-647. Reserved

R4-23-648. Reserved

R4-23-649. Reserved

R4-23-650. Reserved

R4-23-651. Definitions

The following definitions apply to R4-23-651 through R4-23-659:

"Administration" means the giving of a dose of medication to a patient as a result of an order of a medical practitioner.

"Direct copy" means an electronic, facsimile or carbonized copy.

"Dispensing for hospital inpatients" means the interpreting, evaluating, and implementing a medication order including preparing for delivery a drug or device to an inpatient or inpatient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, an inpatient (hereafter referred to as "dispensing").

"Drug distribution" means the delivery of drugs other than "administering" or "dispensing."

"Emergency medical situation" means a condition of emergency in which immediate drug therapy is required for the preservation of health, life, or limb of a person or persons.

"Floor stock" means a supply of essential drugs not labeled for a specific patient and maintained and controlled by the pharmacy at a patient care area for the purpose of timely administration to a patient of the hospital.

"Formulary" means a continually revised compilation of pharmaceuticals (including ancillary information) that reflects the current clinical judgment of the medical staff.

"Hospital pharmacy" means a pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, and is located in a hospital as defined in A.R.S. § 32-1901.

"Inpatient" means any patient who receives non-self-administered drugs from a hospital pharmacy for use while within a facility owned by the hospital.

"Intravenous admixture" means a sterile parenteral solution to which one or more additional drug products have been added.

"Medication order" means a written, electronic, or verbal order from a medical practitioner or a medical practitioner's authorized agent for administration of a drug or device.

"On-call" means a pharmacist is available to:

Consult or provide drug information regarding drug therapy or related issues; or

Dispense a medication order and review a patient's medication order for pharmaceutical and therapeutic feasibility under R4-23-653(E)(2) before any drug is administered to a patient, except as specified in R4-23-653(E)(1).

"Patient care area" means any area for the primary purpose of providing a physical environment that is owned by or operated in conjunction with a hospital, for a patient to obtain health care services, except those areas where a physician, dentist, veterinarian, osteopath, or other medical practitioner engages primarily in private practice.

"Repackaged drug" means a drug product that is transferred by pharmacy personnel from an original manufacturer's container to another container properly labeled for subsequent dispensing.

"Satellite pharmacy" means a work area in a hospital setting under the direction of a pharmacist that is a remote extension of a centrally licensed hospital pharmacy and owned by and dependent upon the centrally licensed hospital pharmacy for administrative control, staffing, and drug procurement.

"Single unit" means a package of medication that contains one discrete pharmaceutical dosage form.

"Supervision" means the process by which a pharmacist directs the activities of hospital pharmacy personnel to a sufficient degree to ensure that all activities are performed accurately, safely, and without risk of harm to patients.

Historical Note

Former Rules 6.7110, 6.7120, and 6.7130; Amended effective August 10, 1978 (Supp. 78-4). Amended subsection (B) effective April 20, 1982 (Supp. 82-2). Section repealed, new Section adopted effective February 7, 1990 (Supp. 90-1). Amended effective November 1, 1993 (Supp. 93-4). Amended effective April 5, 1996 (Supp. 96-2). Amended by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4).

R4-23-652. Hospital Pharmacy Permit

A. The following rules are applicable to all hospitals as defined by A.R.S. § 32-1901 and hospital pharmacies as defined by R4-23-651.

B. Before opening a hospital pharmacy, a person shall obtain a pharmacy permit as specified in R4-23-602 and R4-23-606.

C. Discontinued hospitals. If a hospital license is discontinued by the state Department of Health Services, the pharmacy permittee or pharmacist-in-charge shall follow the procedures described in R4-23-613 for discontinuing a pharmacy.

Historical Note

Former Rules 6.7210, 6.7220, 6.7230, 6.7231, 6.7232, and 6.7233. Section repealed, new Section adopted effective February 7, 1990 (Supp. 90-1). Amended by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4).

R4-23-653. Personnel: Professional or Technician

A. Each hospital pharmacy shall be directed by a pharmacist who is licensed to engage in the practice of pharmacy in Arizona and is referred to as the Director of Pharmacy. The Director of Pharmacy shall be the pharmacist-in-charge, as defined in A.R.S. § 32-1901 or shall appoint a pharmacist-in-charge. The Director of Pharmacy and the pharmacist-in-charge, if a different individual, shall:

1. Be responsible for all the activities of the hospital pharmacy and for meeting the requirements of the Arizona Pharmacy Act and these rules;
2. Ensure that the policies and procedures required by these rules are prepared and implemented;
3. Review biennially and, if necessary, revise the policies and procedures required under these rules;
4. Document the review required under subsection (A)(3);
5. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee; and
6. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its designee.

B. In all hospitals, a pharmacist shall be in the hospital during the time the pharmacy is open for pharmacy services, except for an extreme emergency as defined in R4-23-110. Pharmacy services shall be provided for a minimum of 40 hours per week, unless an exception for less than the minimum hours is made upon written request by the hospital and with express permission of the Board or its designee.

C. In a hospital where the pharmacy is not open 24 hours per day for pharmacy services, a pharmacist shall be "on-call" as defined in R4-23-651 when the pharmacy is closed.

D. The Director of Pharmacy may be assisted by other personnel approved by the Director of Pharmacy in order to operate the pharmacy competently, safely, and adequately to meet the needs of the hospital's patients.

E. Pharmacists. A pharmacist or a pharmacy intern or graduate intern under the supervision of a pharmacist shall perform the following professional practices:

1. Verify a patient's medication order before administration of a drug to the patient, except:
   a. In an emergency medical situation; or
   b. In a hospital where the pharmacy is open less than 24 hours a day for pharmacy services, a pharmacist shall verify a patient's medication order within four hours of the time the pharmacy opens for pharmacy services;
2. Verify a medication order's pharmaceutical and therapeutic feasibility based upon:
   a. The patient's medical condition,
   b. The patient's allergies,
   c. The pharmaceutical and therapeutic incompatibilities, and
   d. The recommended dosage limits;
3. Measure, count, pour, or otherwise prepare and package a drug needed for dispensing, except a pharmacy technician or pharmacy technician trainee may measure, count, pour, or otherwise prepare and package a drug needed for dispensing under the supervision of a pharmacist according to written policies and procedures approved by the Board or its designee;
4. Compound, admix, combine, or otherwise prepare and package a drug needed for dispensing, except a pharmacy technician may compound, admix, combine, or otherwise prepare and package a drug needed for dispensing under the supervision of a pharmacist according to written policies and procedures approved by the Board or its designee;
5. Verify the accuracy, correct procedure, compounding, admixing, combining, measuring, counting, pouring, preparing, packaging, and safety of a drug prepared and packaged by a pharmacy technician or pharmacy technician trainee according to subsections (E)(3) and (4) and according to the policies and procedures in subsection (G);
6. Supervise drug repackaging and check the completed repackaged product as specified in R4-23-402(A);

7. Supervise training and education in aseptic technique and drug incompatibilities for all personnel involved in the admixture of parenteral products within the hospital pharmacy;
8. Consult with the medical practitioner regarding the patient's drug therapy or medical condition;
9. When requested by a medical practitioner, patient, patient's agent, or when the pharmacist deems it necessary, provide consultation with a patient regarding the medication order, patient's profile, or overall drug therapy;
10. Monitor a patient's drug therapy for safety and effectiveness;
11. Provide drug information to patients and health care professionals;
12. Manage the activities of pharmacy technicians, pharmacy technician trainees, other personnel, and systems to ensure that all activities are performed accurately, safely, and without risk of harm to patients;
13. Verify the accuracy of all aspects of the original, completed medication order; and
14. Ensure compliance by pharmacy personnel with a quality assurance program developed by the hospital.

F. Pharmacy technicians and pharmacy technician trainees. Before working as a pharmacy technician or pharmacy technician trainee, an individual shall meet the eligibility and licensure requirements prescribed in 4 A.A.C. 23, Article 11.

G. Pharmacy technician policies and procedures. Before employing a pharmacy technician or pharmacy technician trainee, a Director of Pharmacy or pharmacist-in-charge shall develop the policies and procedures required under R4-23-1104.

H. Pharmacy technician training program.
1. A Director of Pharmacy or pharmacist-in-charge shall comply with the training program requirements of R4-23-1105 based on the needs of the hospital pharmacy;
2. A pharmacy technician or pharmacy technician trainee shall:
   a. Perform only those tasks for which training and competency have been demonstrated; and
   b. Not perform professional practices reserved for a pharmacist, graduate intern, or pharmacy intern in subsection (E), except as specified in subsections (E)(3) and (4).

I. Supervision. A hospital pharmacy's Director of Pharmacy and the pharmacist-in-charge, if a different individual, shall supervise all of the activities and operations of a hospital pharmacy. A pharmacist shall supervise all functions and activities of pharmacy technicians, pharmacy technician trainees, and other hospital pharmacy personnel to ensure that all functions and activities are performed competently, safely, and without risk of harm to patients.

Historical Note

Former Rules 6.7310 and 6.7320; Amended effective August 10, 1978 (Supp. 78-4). Section repealed, new Section adopted effective February 7, 1990 (Supp. 90-1). Amended effective November 1, 1993 (Supp. 93-4). Amended by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4). Amended by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-654. Absence of Pharmacist

A. If a pharmacist will not be on duty in the hospital, the Director of Pharmacy or pharmacist-in-charge shall arrange, before the pharmacist's absence, for the medical staff and other authorized personnel of the hospital to have access to drugs in the remote drug storage area defined in R4-23-110 or in the hospital pharmacy if a drug is not available in a remote drug storage area and is required to treat the immediate needs of a patient. A pharmacist shall be on-call during all absences.

B. If a pharmacist will not be on duty in the hospital pharmacy, the Director of Pharmacy or pharmacist-in-charge shall arrange, before the pharmacist's absence, for the medical staff and other authorized personnel of the hospital to have telephone access to an on-call pharmacist.

C. The hospital pharmacy permittee shall ensure that the hospital pharmacy is not without a pharmacist on duty in the hospital for more than 72 consecutive hours.

D. Remote drug storage area. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital:
1. Develop and maintain an inventory listing of the drugs to be included in a remote drug storage area; and
2. Develop and implement policies and procedures in the same manner described in R4-23-653(A) that ensure proper storage, access, and accountability for drugs in a remote drug storage area.

E. Access to hospital pharmacy. If a drug is not available from a remote drug storage area and the drug is required to treat the immediate needs of a patient whose health may be compromised, the drug may be obtained from the hospital pharmacy according to the requirements of this subsection.
1. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital, develop and implement policies and procedures in the same manner described in R4-23-653(A) to ensure that access to the hospital pharmacy during the pharmacist's absence conforms to the following requirements:
   a. Access is delegated to only one supervisory nurse in each shift;
   b. The policy and name of supervisory nurse is communicated in writing to the medical staff of the hospital;
   c. Access is delegated only to a nurse who has received training from the Director of Pharmacy, pharmacist-in-charge, or Director's designee in the procedures required for proper access, drug removal, and recordkeeping; and
   d. Access is delegated by the supervisory nurse to another nurse only in an emergency.
2. If a nurse to whom authority is delegated to access the hospital pharmacy removes a drug from the hospital pharmacy, the nurse shall:
   a. Record the following information on a form or by another method approved by the Board or its designee:
      i. Patient's name;
      ii. Drug name, strength, and dosage form;
      iii. Quantity of drug removed; and
      iv. Date and time of removal;
   b. Sign or initial, if a corresponding signature is on file in the hospital pharmacy, the form recording the drug removal;
   c. Attach the original or a direct copy of the medication order for the drug to the form recording the drug removal; and
   d. Place the form recording the drug removal conspicuously in the hospital pharmacy.
3. Within four hours after a pharmacist returns from an absence, the pharmacist shall verify all records of drug removal that occurred during the pharmacist's absence according to R4-23-653(E).

Historical Note

Former Rules 6.7410, 6.7420, 6.7430, 6.7440, 6.7450, and 6.7460; Amended subsection (A) effective Aug. 9, 1983 (Supp. 83-4). Section repealed, new Section adopted effective February 7, 1990 (Supp. 90-1). Amended by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4). Amended by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-655. Physical Facility

A. General. A hospital pharmacy permittee shall ensure that the hospital pharmacy has sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations.

B. Minimum area of hospital pharmacy. The minimum area of a hospital pharmacy depends on the type of hospital, the number of beds, and the pharmaceutical services provided. Any hospital pharmacy permit issued or hospital pharmacy remodeled after January 31, 2003 shall provide a minimum hospital pharmacy area, the actual area primarily devoted to drug dispensing and preparation functions, exclusive of bulk drug storage, satellite pharmacy, and office areas that is not less than 500 square feet. The minimum area requirement, not including unusable area, may be varied upon approval by the Board for out-of-the-ordinary conditions or for systems that require less space.

C. The Board may also require that a hospital pharmacy permittee or applicant provide:

1. More than the minimum area if equipment, inventory, personnel, or other factors cause crowding to a degree that interferes with safe pharmacy practice;
2. Additional dispensing, preparation, or storage areas because of the increased number of specific drugs prescribed per day, the increased use of intravenous and irrigating solutions, and the increased use of disposable and prepackaged products;
3. Additional dispensing, preparation, or storage areas to handle investigational drugs, emergency drug kits, chemotherapeutics, alcohol and other flammables, poisons, external preparations, and radioisotopes, and to accommodate quality control procedures; and
4. Additional office space to provide for an increased number of personnel, a drug information library, a poison information library, research support, teaching and conferences, and a waiting area.

D. Hospital pharmacy area. A hospital pharmacy permittee shall ensure that the hospital pharmacy area is enclosed by a permanent barrier or partition from floor to ceiling with entry doors that can be securely locked, constructed according to R4-23-609(F)(1).

E. Hospital pharmacy storage areas. The hospital pharmacy permittee, Director of Pharmacy, or pharmacist-in-charge shall ensure that all undispensed or undistributed drugs are stored in designated areas within the hospital pharmacy or other locked areas under the control of a pharmacist that ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.

Historical Note

Former Rules 6.7471, 6.7472, 6.7473, 6.7474, and 6.7490; Amended effective Aug. 9, 1983 (Supp. 83-4). Section repealed, new Section adopted effective February 7, 1990 (Supp. 90-1). Correction to Table 1 ("spare feet" changed to "square feet") (Supp. 91-1). Amended by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4).

R4-23-656. Sanitation and Equipment

A hospital pharmacy permittee or Director of Pharmacy shall ensure that a hospital pharmacy:

1. Has a professional reference library consisting of hard-copy or electronic media appropriate for the scope of pharmacy services provided by the hospital;
2. Has a sink, other than a sink in a toilet facility, that:
   a. Has hot and cold running water;
   b. Is within the hospital pharmacy area for use in preparing drug products; and
   c. Is maintained in a sanitary condition and in good repair;
3. Maintains a room temperature within a range compatible with the proper storage of drugs;
4. Has a refrigerator and freezer with a temperature maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing; and
5. Has a designated area for a laminar air flow hood and other supplies required for the preparation of sterile products as specified in R4-23-670.

Historical Note

Former Rule 6.7480. Section repealed, new Section adopted effective February 7, 1990 (Supp. 90-1). Amended by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4).

R4-23-657. Security

A. Personnel security standards. A Director of Pharmacy shall ensure that:

1. No one is permitted in the pharmacy unless a pharmacist is present except as provided in this Section and R4-23-654. If only one pharmacist is on duty in the pharmacy and that pharmacist must leave the pharmacy for an emergency or patient care duties, nonpharmacist personnel may remain in the pharmacy to perform duties as outlined in R4-23-653, provided that all C-II controlled substances are secured to prohibit access by other than a pharmacist, and that the pharmacist remains available in the hospital;
2. All hospital pharmacy areas are kept locked by key or programmable lock to prevent access by unauthorized personnel; and
3. Pharmacists, pharmacy or graduate interns, pharmacy technicians, pharmacy technician trainees, and other personnel working in the pharmacy wear identification badges, including name and position, whenever on duty.

B. Prescription blank security. The Director of Pharmacy shall develop and implement policies and procedures in the same manner described in R4-23-653(A) for the safe distribution and control of prescription blanks bearing identification of the hospital.

Historical Note

Former Rule 6.7500; Amended effective Aug. 9, 1983 (Supp. 83-4). Section repealed, new Section adopted effective February 7, 1990 (Supp. 90-1). Amended by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4). Amended by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-658. Drug Distribution and Control

A. General. The Director of Pharmacy or pharmacist-in-charge shall in consultation with the medical staff, develop and implement written policies and procedures in the same manner described in R4-23-653(A) for the effective operation of a drug distribution system that optimizes patient safety.

B. Responsibility. The Director of Pharmacy is responsible for the safe and efficient procurement, dispensing, distribution, administration, and control of drugs, including the following:
1. In consultation with the appropriate department personnel and medical staff committee, develop a medication formulary for the hospital;
2. Proper handling, distribution, and recordkeeping of investigational drugs; and
3. Regular inspections of drug storage and preparation areas within the hospital.

C. Physician orders. A Director of Pharmacy or pharmacist-in-charge shall ensure that:
1. Drugs are dispensed from the hospital pharmacy only upon a written order, direct copy or facsimile of a written order, or verbal order of an authorized medical practitioner; and
2. A pharmacist reviews the original, direct or facsimile copy, or verbal order before an initial dose of medication is administered, except as specified in R4-23-653(E)(1).

D. Labeling. A Director of Pharmacy or pharmacist-in-charge shall ensure that all drugs distributed or dispensed by a hospital pharmacy are packaged in appropriate containers and labeled as follows:
1. For use inside the hospital.
   a. Labels for all single unit packages contain at a minimum, the following information:
      i. Drug name, strength, and dosage form;
      ii. Lot number and beyond-use-date; and
      iii. Appropriate auxiliary labels;
   b. Labels for repackaged preparations contain at a minimum the following information:
      i. Drug name, strength, and dosage form;
      ii. Lot number and beyond-use-date;
      iii. Appropriate auxiliary labels; and
      iv. Mechanism to identify pharmacist accountable for repackaging;
   c. Labels for all intravenous admixture preparations contain at a minimum the following information:
      i. Patient's name and location;
      ii. Name and quantity of the basic parenteral solution;
      iii. Name and amount of drug added;
      iv. Date of preparation;
      v. Beyond-use-date and time;
      vi. Guidelines for administration;
      vii. Appropriate auxiliary label or precautionary statement; and
      viii. Initials of pharmacist responsible for admixture preparation; and
2. For use outside the hospital. Any drug dispensed to a patient by a hospital pharmacy that is intended for self-administration outside of the hospital is labeled as specified in A.R.S. §§ 32-1963.01(C) and 32-1968(D) and A.A.C. R4-23-402.

E. Controlled substance accountability. A Director of Pharmacy or pharmacist-in-charge shall ensure that effective policies and procedures are developed and implemented in the same manner described in R4-23-653(A) regarding the use, accountability, and recordkeeping of controlled substances in the hospital, including the use of locked storage areas when controlled substances are stored in patient care areas.

F. Emergency services dispensing. If a hospital permits dispensing of drugs from the emergency services department when the pharmacy is unable to provide this service, the Director of Pharmacy, in consultation with the appropriate department personnel and medical staff committee shall develop and implement written policies and procedures in the same manner described in R4-23-653(A) for dispensing drugs for outpatient use from the hospital's emergency services department. The policies and procedures shall include the following requirements:
1. Drugs are dispensed only to patients who have been admitted to the emergency services department;
2. Drugs are dispensed only by an authorized medical practitioner, not a designee or agent;
3. The nature and type of drugs available for dispensing are designed to meet the immediate needs of the patients treated within the hospital;
4. Drugs are dispensed only in quantities sufficient to meet patient needs until outpatient pharmacy services are available;
5. Drugs are prepackaged by a pharmacist or a pharmacy intern, graduate intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist in suitable containers and appropriately prelabeled with the drug name, strength, dosage form, quantity, manufacturer, lot number, beyond-use-date, and any appropriate auxiliary labels;
6. Upon dispensing, the authorized medical practitioner completes the label on the prescription container that complies with the requirements of R4-23-658(D); and
7. The hospital pharmacy maintains a dispensing log, hard-copy prescription, or electronic record, approved by the Board or its designee and includes the patient name and address, drug name, strength, dosage form, quantity, directions for use, medical practitioner's signature or identification code, and DEA registration number, if applicable.

Historical Note

Former Rules 6.7610, 6.7620, and 6.7710; Amended effective Aug. 9, 1983 (Supp. 83-4). Section repealed, new Section adopted effective February 7, 1990 (Supp. 90-1). Correction to subsection (I)(5) ("unnecessary" changed to "necessary") (Supp. 91-1). Amended effective November 1, 1993 (Supp. 93-4). Amended by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4). Amended by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-659. Administration of Drugs

A. Self-administration. A hospital shall not allow self-administration of medications by a patient unless the Director of Pharmacy or pharmacist-in-charge, in consultation with the appropriate department personnel and medical staff committee, develops and implements policies and procedures for self-administration of medications by a patient in the same manner described in R4-23-653(A). The policies and procedures shall specify that self-administration of medications, if allowed, occurs only when:
1. Specifically ordered by a medical practitioner, and
2. The patient is educated and trained in the proper manner of self-administration.

B. Drugs brought in by a patient. If a hospital allows a patient to bring a drug into the hospital and before a patient brings a drug into the hospital, the Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate department personnel and medical staff committee, develop and implement policies and procedures for a patient-owned drug brought into the hospital in the same manner described in R4-23-653(A). The policies and procedures shall specify the following criteria for a patient-owned drug brought into the hospital:

1. When policy allows the administration of a patient-owned drug, the drug is not administered to the patient unless:
   a. A pharmacist or medical practitioner identifies the drug, and
   b. A medical practitioner writes a medication order specifying administration of the identified patient-owned drug; and
2. If a patient-owned drug will not be used during the patient's hospitalization, the hospital pharmacy's personnel shall:
   a. Package, seal, and give the drug to the patient's agent for removal from the hospital; or
   b. Package, seal, and store the drug for return to the patient at the time of discharge from the hospital.

C. Drug samples. The Director of Pharmacy or pharmacist-in-charge is responsible for the receipt, storage, distribution, and accountability of drug samples within the hospital, including developing and implementing specific policies and procedures in the same manner described in R4-23-653(A) regarding drug samples.

Historical Note
Former Rules 6.7720, 6.7730, 6.7740, 6.7760, 6.7770, 6.7780, 6.7800, 6.7810, 6.7820, 6.7830, 6.7840, 6.7850, 6.7871, 6.7872, and 6.7873; Amended effective Aug. 9, 1983 (Supp. 83-4). Section repealed, new Section adopted effective February 7, 1990 (Supp. 90-1). Correction to Section heading ("rules" changed to "roles") (Supp. 91-1). Section repealed; new Section made by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4). Amended by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-660. Investigational Drugs

The Director of Pharmacy or pharmacist-in-charge shall ensure that:

1. The following information concerning an investigational drug is available for use by hospital personnel:
   a. Composition,
   b. Pharmacology,
   c. Adverse reactions,
   d. Administration guidelines, and
   e. All other available information concerning the drug, and
2. An investigational drug is:
   a. Properly stored in, labeled, and dispensed from the pharmacy, and
   b. Not dispensed before the drug is approved by the appropriate medical staff committee of the hospital.

Historical Note
Former Rules 6.7881, 6.7882, and 6.7883; Amended subsection (A) effective Aug. 9, 1983 (Supp. 83-4). Repealed, new Section adopted effective February 7, 1990 (Supp. 90-1). Section repealed; new Section made by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4).

R4-23-661. Repealed

Historical Note
Former Rules 6.7910, 6.7920, 6.7930, 6.7940, and 6.7950. Section repealed, new Section adopted effective February 7, 1990 (Supp. 90-1). Section repealed by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4).

R4-23-662. Repealed

Historical Note
Adopted effective February 7, 1990 (Supp. 90-1). Section repealed by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4).

R4-23-663. Repealed

Historical Note
Adopted effective February 7, 1990 (Supp. 90-1). Amended effective November 1, 1993 (Supp. 93-4). Section repealed by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4).

R4-23-664. Repealed

Historical Note
Adopted effective February 7, 1990 (Supp. 90-1). Subsection label removed (Supp. 91-1). Section repealed by final rulemaking at 8 A.A.R. 4902, effective January 5, 2003 (Supp. 02-4).

R4-23-665. Reserved

R4-23-666. Reserved

R4-23-667. Reserved

R4-23-668. Reserved

R4-23-669. Reserved

R4-23-670. Sterile Pharmaceutical Products Pharmacy

A. Prior to compounding sterile pharmaceutical products, the owner shall obtain a pharmacy permit in compliance with R4-23-606.

B. In addition to the space requirement of R4-23-609(A) and R4-23-655(B), there shall be a minimum 60 square feet of contiguous floor space dedicated to the purpose of compounding sterile pharmaceutical products. The sterile-compounding area shall be isolated from other pharmacy functions, have restricted entry or access, and be free from unnecessary disturbances in air flow. This area shall have nonporous and cleanable surfaces. The Board may also require more than the minimum area in instances where equipment, inventory, personnel, or other factors cause crowding to such a degree as to interfere with safe pharmacy practice.

C. Equipment required to compound sterile products shall, in addition to the requirements in R4-23-611 and R4-23-612, include:

1. Environmental control devices capable of maintaining a compounding area environment equivalent to "class 100 conditions" as described in the Federal Standard 209 Clean Room and Work Station Requirements: Controlled Environment, publication FED-STD-209D, June 15, 1988, edition which includes January 28, 1991, changes, incorporated herein by reference and on file with the Office of the Secretary of State. Devices capable of meeting these standards include but are not limited to: laminar airflow hoods, hepa-filtered zonal airflow devices, and biological safety cabinets.
2. Disposal containers designed for needles, syringes, and other material used in compounding sterile products and, if applicable, separate containers to dispose of cytotoxic, chemotherapeutic, and infectious waste products.
3. Freezer/storage units with thermostatic control and thermometer; temperature-controlled delivery containers.
4. Infusion devices and accessories, if applicable.

5. Reference library shall, in addition to the requirements of R4-23-612, include current references pertinent to the preparation of sterile pharmaceutical products.

D. Prior to compounding sterile pharmaceutical products, the pharmacist-in-charge shall prepare and have available for inspection by the Board or its designee a policy and procedure manual addressing the following subjects:
1. Clinical services and drug monitoring;
2. Controlled substances;
3. Cytotoxics handling, storage, and disposal;
4. Disposal of unused supplies and medications;
5. Drug administration, including guidelines for the first dosing of the medication;
6. Drug product procurement;
7. Drug compounding, dispensing, and storage;
8. Duties and qualifications of professional and support staff;
9. Equipment maintenance and inventory;
10. Handling of infectious wastes;
11. Infusion devices and drug delivery systems;
12. Investigational drugs and their protocols;
13. Patient profiles;
14. Patient education and safety which includes, but is not limited to, provisions for the assessment of the living environment of patients receiving sterile products;
15. Quality assurance procedures which, in addition to the requirements set forth in R4-23-662, shall include:
    a. Recall procedures;
    b. Storage and beyond-use dating as defined in R4-23-110;
    c. Educational procedures for professional staff, support staff, and patient;
    d. Sterile procedures including a log of the temperature of the refrigerator/freezer, routing maintenance, and record of hood certification;
    e. Sterility testing with documentation of end product and process testing;
16. Recordkeeping;
17. Sanitation;
18. Security;
19. Delivery of sterile products:
    a. Transportation;
    b. Emergency provision.

E. The nondistributive roles of the pharmacist may include but are not limited to chart reviews, audits, drug therapy monitoring, committee participation, drug information, in-service training of pharmacy and other health professionals.

Historical Note
Adopted effective November 1, 1993 (Supp. 93-4).

R4-23-671. General Requirements for Limited-service Pharmacy

A. Before opening a limited-service pharmacy, a person shall obtain a permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and R4-23-606.

B. The limited-service pharmacy permittee shall secure the limited-service pharmacy by conforming with the following standards:
1. Permit no one to be in the limited-service pharmacy unless the pharmacist-in-charge or a pharmacist authorized by the pharmacist-in-charge is present;
2. Require the pharmacist-in-charge to designate in writing, by name, title, and specific area, those persons who will have access to particular areas of the limited-service pharmacy;
3. Implement procedures to guard against theft or diversion of drugs, including controlled substances; and
4. Require all persons working in the limited-service pharmacy to wear badges, with their names and titles, while on duty.

C. To obtain permission to deviate from the minimum area requirement set forth in R4-23-609, R4-23-673, or R4-23-682, a limited-service pharmacy permittee shall submit a written request to the Board and include documentation that the deviation will facilitate experimentation or technological advances in the practice of pharmacy as defined in A.R.S. § 32-1901. If the Board determines the requested deviation from the minimum area requirement will enhance the practice of pharmacy and benefit the public, the Board shall grant the requested deviation.

D. The Board shall require more than the minimum area in a limited-service pharmacy when the Board determines that equipment, personnel, or other factors in the limited-service pharmacy cause crowding that interferes with safe pharmacy practice.

E. Before dispensing from a limited-service pharmacy, the limited-service pharmacy permittee or pharmacist-in-charge shall:
1. Prepare and implement written policies and procedures for pharmacy operations and drug distribution,
2. Review biennially and if necessary revise the policies and procedures required under subsection (E)(1),
3. Document the review required under subsection (E)(2),
4. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee, and
5. Make the policies and procedures available in the pharmacy for employee reference and inspection by the Board or its designee.

Historical Note
Adopted effective April 5, 1996 (Supp. 96-2). Amended by final rulemaking at 9 A.A.R. 1064, effective May 4, 2003 (Supp. 03-1).

R4-23-672. Limited-service Correctional Pharmacy

A. The limited-service pharmacy permittee shall ensure that the limited-service correctional pharmacy complies with the standards for area, personnel, security, sanitation, equipment, drug distribution and control, administration of drugs, drug source, quality assurance, investigational drugs, and inspections as set forth in R4-23-608, R4-23-609(A) through (D) and (F) through (H), R4-23-610(A), R4-23-611, R4-23-612, R4-23-653(D), except (2)(e), R4-23-658(B) through (H), and R4-23-660 through R4-23-664.

B. The pharmacist-in-charge of a limited-service correctional pharmacy shall authorize only pharmacists, interns, drug inspectors, peace officers, and correctional officers acting in their official capacities, supportive personnel, and other designated personnel to be in the limited-service correctional pharmacy.

C. When no pharmacist will be on duty in the correctional facility, the pharmacist-in-charge shall arrange, before there is no pharmacist on duty, for the medical staff and other authorized personnel of the correctional facility to have access to drugs in remote drug storage areas or, if a drug is not available in a remote drug storage area and is required to treat the immediate needs of a patient, in the limited-service correctional pharmacy.
1. The pharmacist-in-charge shall, in consultation with the appropriate committee of the correctional facility, develop and implement procedures to ensure that remote drug storage areas:

a. Contain only properly labeled drugs that might reasonably be needed and can be administered safely during the absence of a pharmacist,
b. Contain drugs packaged only in amounts sufficient for immediate therapeutic requirements,
c. Are accessible only with a physician's written order,
d. Provide a written record of each drug withdrawn,
e. Are inventoried at least once each week, and
f. Are audited for compliance with the requirements of this rule at least once each month.

2. The pharmacist-in-charge shall, in consultation with the appropriate committee of the correctional facility, develop and implement procedures to ensure that access to the limited-service correctional pharmacy when no pharmacist is on duty conforms to the following requirements:
a. Is delegated to only one nurse, who is in a supervisory position;
b. Is communicated in writing to medical staff of the correctional facility;
c. Is delegated only to a nurse who has received training from the pharmacist-in-charge in proper methods of access, removal of drugs, and records and procedures required; and
d. Is delegated by the supervisory nurse to another nurse only in emergencies.

3. When a nurse to whom authority to access the limited-service correctional pharmacy is delegated removes a drug from the limited-service correctional pharmacy, the nurse shall:
a. Record the following information on a form:
i. Patient's name,
ii. Name of the drug and its strength and dosage form,
iii. Dose prescribed,
iv. Amount of drug removed, and
v. Date and time of removal;
b. Sign the form recording the drug removal;
c. Attach the original or a direct copy of a physician's written order for the drug to the form recording the drug removal; and
d. Place the form recording the drug removal conspicuously in the limited-service correctional pharmacy.

4. Within four hours after a pharmacist in the limited-service correctional pharmacy returns to duty following an absence in which the limited-service correctional pharmacy was accessed by a nurse to whom authority had been delegated, the pharmacist shall verify all records of drug removal in accordance with R4-23-402.

D. When no pharmacist will be on duty in the correctional facility, the pharmacist-in-charge shall arrange, before there is no pharmacist on duty, for the medical staff and other authorized personnel of the correctional facility to have telephone access to a pharmacist.

E. The limited-service pharmacy permittee shall ensure that the limited-service correctional pharmacy is without a pharmacist on duty for no more than 96 consecutive hours.

F. In addition to the requirements of R4-23-671, the limited-service pharmacy permittee shall secure the limited-service correctional pharmacy by conforming with the following standards:
1. Permit no one to be in the limited-service correctional pharmacy unless a pharmacist is on duty except:
a. As provided in subsection (C)(3) when no pharmacist is on duty; or
b. Pharmacy technicians may remain to perform duties outlined in R4-23-653(D)(2), except subsection (D)(2)(e), when a pharmacist is on duty and available in the correctional facility but temporarily absent from the pharmacy, provided all controlled substances are secured in a manner that prohibits access by persons other than a pharmacist; and

2. Provide keyed or programmable locks to all areas of the limited-service correctional pharmacy.

G. The pharmacist-in-charge of a limited-service correctional pharmacy shall ensure that the written policies and procedures for pharmacy operations and drug distribution within the correctional facility include the following:
1. Physicians' orders, prescription orders, or both;
2. Authorized abbreviations;
3. Formulary system;
4. Clinical services and drug utilization management including:
a. Participation in drug selection,
b. Drug utilization reviews,
c. Inventory audits,
d. Patient outcome monitoring,
e. Committee participation,
f. Drug information, and
g. Education of pharmacy and other health professionals;
5. Duties and qualifications of professional and support staff;
6. Products of abuse and contraband medications;
7. Controlled substances;
8. Drug administration;
9. Drug product procurement;
10. Drug compounding, dispensing, and storage;
11. Stop orders;
12. Pass/Discharge medications;
13. Investigational drugs and their protocols;
14. Patient profiles;
15. Quality management procedures for:
a. Adverse drug reactions;
b. Drug recalls;
c. Expired and beyond-use-date drugs;
d. Medication or dispensing errors;
e. Drug storage; and
f. Education of professional staff, support staff, and patients;
16. Recordkeeping;
17. Sanitation;
18. Security;
19. Access to remote drug storage areas by non-pharmacists; and
20. Access to limited-service correctional pharmacy by non-pharmacists.

Historical Note

Adopted effective April 5, 1996 (Supp. 96-2).

R4-23-673. Limited-service Mail-order Pharmacy

A. The limited-service pharmacy permittee shall design and construct the limited-service mail-order pharmacy to conform with the following requirements:
1. A dispensing area devoted to stocking, compounding, and dispensing prescription medications, which is physically separate from a non-dispensing area devoted to non-dispensing pharmacy services;
2. A dispensing area of at least 300 square feet if three or fewer persons work in the dispensing area simultaneously;

3. A dispensing area that provides 300 square feet plus 60 square feet for each person in excess of three persons if more than three persons work in the dispensing area simultaneously;
4. Space in the dispensing area permits efficient pharmaceutical practice, free movement of personnel, and visual surveillance by the pharmacist;
5. A non-dispensing area of at least 30 square feet for each person working simultaneously in the non-dispensing area; and
6. Space in the non-dispensing area permits free movement of personnel and visual surveillance by the pharmacist; or

B. The limited-service pharmacy permittee shall design and construct the limited-service mail-order pharmacy to conform with the following requirements:
1. A contiguous area in which both dispensing and non-dispensing pharmacy services are provided;
2. A contiguous area of at least 300 square feet if three or fewer persons work in the area simultaneously;
3. A contiguous area that provides 300 square feet plus 60 square feet for each person in excess of three persons if more than three persons work in the area simultaneously; and
4. Space in the contiguous area permits efficient pharmaceutical practice, free movement of personnel, and visual surveillance by the pharmacist.

C. The limited-service pharmacy permittee shall ensure that the limited-service mail-order pharmacy complies with the standards for area, personnel, security, sanitation, and equipment set forth in R4-23-608, R4-23-609(B) through (H), R4-23-610 (A) and (C) through (F), R4-23-611, and R4-23-612.

D. The pharmacist-in-charge of a limited-service mail-order pharmacy shall authorize only pharmacists, interns, pharmacy technicians, pharmacy technician trainees, drug inspectors, peace officers acting in their official capacities, support personnel, and other designated personnel to be in the limited-service mail-order pharmacy.

E. The pharmacist-in-charge of a limited-service mail-order pharmacy shall ensure that prescription medication is delivered to the patient or locked in the dispensing area when a pharmacist is not present in the pharmacy.

F. In addition to the delivery requirements of R4-23-402, the limited-service pharmacy permittee shall, during regular hours of operation but not less than five days and a minimum 40 hours per week, provide toll-free telephone service to facilitate communication between patients and a pharmacist who has access to patient records at the limited-service mail-order pharmacy. The limited-service pharmacy permittee shall disclose this toll-free number on a label affixed to each container of drugs dispensed from the limited-service mail-order pharmacy.

G. The pharmacist-in-charge of a limited-service mail-order pharmacy shall ensure that the written policies and procedures for pharmacy operations and drug distribution include the following:
1. Prescription orders;
2. Clinical services and drug utilization management for:
   a. Drug utilization reviews,
   b. Inventory audits,
   c. Patient-outcome monitoring,
   d. Drug information, and
   e. Education of pharmacy and other health professionals;
3. Duties and qualifications of professional and support staff;
4. Controlled substances;
5. Drug product procurement;
6. Drug compounding, dispensing, and storage;
7. Patient profiles;
8. Quality management procedures for:
   a. Adverse drug reactions,
   b. Drug recalls,
   c. Expired and beyond-use-date drugs,
   d. Medication or dispensing errors, and
   e. Education of professional and support staff;
9. Recordkeeping;
10. Sanitation;
11. Security;
12. Drug delivery requirements for:
   a. Transportation,
   b. Security,
   c. Temperature and other environmental controls,
   d. Emergency provisions, and
13. Patient education.

Historical Note

Adopted effective April 5, 1996 (Supp. 96-2). Amended by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-674. Limited-service Long-term Care Pharmacy

A. A limited-service pharmacy permittee shall ensure that the limited-service long-term care pharmacy complies with:
1. The general requirements of R4-23-671;
2. The professional practice standards of Article 4 and Article 11; and
3. The permits and drug distribution standards of R4-23-606 through R4-23-612, R4-23-670, and this Section.

B. If a limited-service long-term care pharmacy permittee contracts with a long-term care facility as a Provider Pharmacy, as defined in R4-23-110, the limited-service long-term care pharmacy permittee shall ensure that:
1. The limited-service long-term care pharmacy employs or contracts with a long-term care consultant pharmacist; and
2. The long-term care consultant pharmacist and the pharmacist-in-charge of the limited-service long-term care pharmacy comply with R4-23-701, R4-23-701.01, R4-23-701.02, and R4-23-701.03, and this Section.

C. The limited-service long-term care pharmacy permittee or pharmacist-in-charge shall ensure that prescription medication is delivered to the patient's long-term care facility or locked in the dispensing area of the pharmacy when a pharmacist is not present in the pharmacy.

D. The pharmacist-in-charge of a limited-service long-term care pharmacy shall authorize only those individuals listed in R4-23-610(B) to be in the limited-service long-term care pharmacy.

E. In consultation with the long-term care facility's medical director and director of nursing, the long-term care consultant pharmacist and pharmacist-in-charge of the long-term care facility's provider pharmacy may develop, if necessary, a medication formulary for the long-term care facility that ensures the safe and efficient procurement, dispensing, distribution, administration, and control of drugs in the long-term care facility.

F. The limited-service long-term care pharmacy permittee or pharmacist-in-charge shall ensure that the written policies and procedures required in R4-23-671(E) include the following:
1. Clinical services and drug utilization management for:
   a. Drug utilization reviews,
   b. Inventory audits,
   c. Patient outcome monitoring,
   d. Drug information, and

e. Education of pharmacy and other health professionals;
2. Controlled substances;
3. Drug compounding, dispensing, and storage;
4. Drug delivery requirements for:
a. Transportation,
b. Security,
c. Temperature and other environmental controls, and
d. Emergency provisions;
5. Drug product procurement;
6. Duties and qualifications of professional and support staff;
7. Emergency drug supply unit procedures;
8. Formulary, including development, review, modification, use, and documentation, if applicable;
9. Patient profiles;
10. Patient education;
11. Prescription orders;
12. Quality management procedures for:
a. Adverse drug reactions,
b. Drug recalls,
c. Expired and beyond-use-date drugs,
d. Medication or dispensing errors, and
e. Education of professional and support staff;
13. Recordkeeping;
14. Sanitation; and
15. Security.

Historical Note

New Section made by final rulemaking at 9 A.A.R. 1064, effective May 4, 2003 (Supp. 03-1). Amended by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-675. Reserved

R4-23-676. Reserved

R4-23-677. Reserved

R4-23-678. Reserved

R4-23-679. Reserved

R4-23-680. Reserved

R4-23-681. General Requirements for Limited-service Nuclear Pharmacy

A. To be an authorized nuclear pharmacist, a pharmacist shall:
1. Hold a current pharmacist license issued by the Board; and
2. Be certified as a nuclear pharmacist by:
a. The Board of Pharmaceutical Specialties, or
b. A similar group recognized by the Arizona State Board of Pharmacy; or
3. Satisfy each of the following requirements:
a. Meet minimal standards of training for status as an authorized user of radioactive material, as specified by the Arizona Radiation Regulatory Agency and the United States Nuclear Regulatory Commission;
b. Submit certification of completion of a Board-approved nuclear pharmacy training program or other training program recognized by the Arizona Radiation Regulatory Agency, with 200 hours of didactic training in the following areas:
i. Radiation physics and instrumentation,
ii. Radiation protection,
iii. Mathematics pertaining to the use and measurement of radioactivity,
iv. Radiation biology, and
v. Radiopharmaceutical chemistry;
c. Submit evidence of a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of an authorized nuclear pharmacist in the following areas:
i. Procuring radioactive materials;
ii. Compounding radiopharmaceuticals;
iii. Performing routine quality control procedures;
iv. Dispensing radiopharmaceuticals;
v. Distributing radiopharmaceuticals;
vi. Implementing basic radiation protection procedures; and
vii. Consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public; and
d. Submit written certification, signed by a preceptor who is an authorized nuclear pharmacist, that the above training was satisfactorily completed.

B. Radiopharmaceuticals are prescription-only drugs that require specialized techniques in their handling and testing, to obtain optimum results and minimize hazards.
1. A person shall not sell, barter, or otherwise dispose of, or be in possession of any radiopharmaceutical except under the conditions detailed in A.R.S. § 32-1929.
2. A person shall not manufacture, compound, sell, or dispense any radiopharmaceutical unless the person is a pharmacist or a pharmacy intern acting under the direct supervision of a pharmacist in accordance with A.R.S. § 32-1961 and these rules, with the exception of the following, if the following are licensed by the Arizona Radiation Regulatory Agency to use radiopharmaceuticals in compliance with A.R.S. § 30-673;
a. A medical practitioner who administers a radiopharmaceutical to the medical practitioner's patient as provided in A.R.S. § 32-1921(A),
b. A hospital nuclear medicine department, and
c. A medical practitioner's office.
3. The Board shall cooperate with the Arizona Radiation Regulatory Agency and other interested state and federal agencies, in the enforcement of these rules for the protection of the public. This cooperation may include exchange of licensing and other information, joint inspections, and other activities where indicated.

C. In addition to compliance with all the applicable federal and state laws and rules governing drugs, whether radioactive or not, a limited-service nuclear pharmacy permittee shall comply with all laws and rules of the Arizona Radiation Regulatory Agency and the U.S. Nuclear Regulatory Commission, including emergency and safety provisions.

D. A limited-service nuclear pharmacy permittee shall comply with the education, experience, and licensing requirements of the Arizona Radiation Regulatory Agency.

E. A limited-service nuclear pharmacy permittee shall ensure that radiopharmaceuticals are transferred only to a person or firm that holds a current Radioactive Materials License issued by the Arizona Radiation Regulatory Agency.

Historical Note

Adopted effective December 3, 1974 (Supp. 75-1). Amended subsections (A), (C) and (D) effective Aug. 12, 1988 (Supp. 88-3). Amended effective July 8, 1997 (Supp. 97-3).

R4-23-682. Limited-service Nuclear Pharmacy

A. Before operating a limited-service nuclear pharmacy, a person shall obtain a permit in compliance with A.R.S. §§ 32-1929, 32-1930, and 32-1931, and R4-23-606.

B. A permit to operate a limited-service nuclear pharmacy shall be issued only to a person who is or employs an authorized nuclear pharmacist and holds a current Arizona Radiation Regulatory Agency Radioactive Materials License. A limited-service nuclear pharmacy permittee that fails to maintain a current Arizona Radiation Regulatory Agency Radioactive Materials License shall be immediately suspended pending revocation by the Board. A limited-service nuclear pharmacy permittee shall have copies of Arizona Radiation Regulatory Agency inspection reports available upon request for Board inspection.

1. A limited-service nuclear pharmacy permittee shall designate an authorized nuclear pharmacist as the pharmacist-in-charge. The pharmacist-in-charge shall be responsible to the Board:
   a. For the operations of the pharmacy related to the practice of pharmacy and distribution of drugs and devices;
   b. For communicating Board directives to the management, pharmacists, interns, and other personnel of the pharmacy; and
   c. For the pharmacy's compliance with all federal and state pharmacy laws and rules.
2. An authorized nuclear pharmacist shall directly supervise all personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs.
3. An authorized nuclear pharmacist shall be present whenever the limited-service nuclear pharmacy is open for business.

C. A limited-service nuclear pharmacy permittee shall ensure that the limited-service nuclear pharmacy complies with the standards for personnel, area, security, sanitation, and general requirements in R4-23-608, R4-23-609, R4-23-610, R4-23-611, and R4-23-671.

1. A limited-service nuclear pharmacy shall contain separate areas for:
   a. Preparing and dispensing radiopharmaceuticals,
   b. Receiving and shipping radiopharmaceuticals,
   c. Storing radiopharmaceuticals, and
   d. Decaying radioactive waste.
2. The Board may require more than the minimum area in instances where equipment, inventory, personnel, or other factors cause crowding to a degree that interferes with safe pharmacy practice.

D. The pharmacist-in-charge shall designate in writing, by title and specific area, the persons who may have access to particular pharmacy areas.

E. A limited-service nuclear pharmacy permittee shall maintain records of acquisition, inventory, and disposition of radiopharmaceuticals, other radioactive substances, and other drugs in accordance with federal and state statutes and rules.

1. A prescription order, in addition to the requirements in A.R.S. § 32-1968(C) and R4-23-407(A), shall contain:
   a. The date and time of calibration of the radiopharmaceutical,
   b. The name of the procedure for which the radiopharmaceutical is prescribed, and
   c. The words "Physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product.
2. The lead container used to store and transport a radiopharmaceutical shall have a label that, in addition to the requirements in A.R.S. § 32-1968(D), includes:
   a. The date and time of calibration of the radiopharmaceutical,
   b. The name of the radiopharmaceutical,
   c. The molybdenum 99 content to USP limits,
   d. The name of the procedure for which the radiopharmaceutical is prescribed,
   e. The words "Physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product,
   f. The words "Caution: Radioactive Material," and
   g. The standard radiation symbol.
3. The radiopharmaceutical container shall have a label that includes:
   a. The date and time of calibration of the radiopharmaceutical;
   b. The name of the patient, recorded before dispensing, if the radiopharmaceutical is therapeutic or for a blood product;
   c. The words "Physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product;
   d. The name of the radiopharmaceutical;
   e. The dose of radiopharmaceutical;
   f. The serial number;
   g. The words "Caution: Radioactive Material"; and
   h. The standard radiation symbol.

F. The following minimum requirements are in addition to the requirements of the Arizona Radiation Regulatory Agency, the applicable U.S. Nuclear Regulatory Commission regulations, and the applicable regulations of the federal Food and Drug Administration. A limited-service nuclear pharmacy permittee shall provide:

1. In addition to the minimum pharmacy area requirements in R4-23-609:
   a. An area for the storing, compounding, and dispensing of radiopharmaceuticals completely separate from pharmacy areas for nonradioactive drugs;
   b. A minimum of 80 sq. ft. for a hot lab and storage area; and
   c. A minimum of 300 sq. ft. of compounding and dispensing area;
2. The following equipment:
   a. Fume hood, approved by the Arizona Radiation Regulatory Agency;
   b. Laminar flow hood;
   c. Dose calibrator;
   d. Refrigerator;
   e. Prescription balance, Class A, and weights;
   f. Well scintillation counter;
   g. Incubator oven;
   h. Microscope;
   i. Equipment to produce a typed or mechanically printed label;
   j. Equipment to produce mechanically printed numbers;
   k. An assortment of labels, including prescription labels and cautionary and warning labels;
   l. Glassware necessary for compounding and dispensing radiopharmaceuticals as required by the Arizona Radiation Regulatory Agency;
   m. Other equipment necessary for radiopharmaceutical quality control for products compounded or dispensed as required by the Arizona Radiation Regulatory Agency;
   n. Current antidote and drug interaction information; and
   o. Regional poison control phone number prominently displayed in the pharmacy area;

3. Supplies necessary for compounding and dispensing radiopharmaceuticals as required by the Arizona Radiation Regulatory Agency;
4. A professional reference library consisting of a minimum of one current reference or text addressing each of the following subject areas:
   a. Therapeutics,
   b. Nuclear pharmacy practice, and
   c. Imaging;
5. Current editions and supplements of:
   a. A.R.S. §§ 30-651 through 30-696 pertaining to the Arizona Radiation Regulatory Agency,
   b. Rules of the Arizona Radiation Regulatory Agency,
   c. Regulations of the federal Food and Drug Administration pertaining to radioactive drugs,
   d. Arizona Pharmacy Act and rules,
   e. Arizona Uniform Controlled Substances Act, and
   f. Radiological Health Handbook.

G. The pharmacist-in-charge of a limited-service nuclear pharmacy shall prepare and implement written policies and procedures for pharmacy operations and drug distribution.

H. The written policies and procedures of a limited-service nuclear pharmacy shall include the following:
1. Prescription orders;
2. Clinical services and drug utilization management including:
   a. Drug utilization reviews,
   b. Inventory audits,
   c. Patient outcome monitoring,
   d. Drug information, and
   e. Education of pharmacy and other health professionals;
3. Duties and qualifications of professional and support staff;
4. Radioactive material handling, storage, and disposal;
5. Drug product procurement;
6. Drug compounding, dispensing, and storage;
7. Investigational drugs and their protocols;
8. Patient profiles;
9. Quality management procedures for:
   a. Adverse drug reaction reports;
   b. Drug recall;
   c. Expired and beyond-use-date drugs;
   d. Medication or dispensing errors;
   e. Radiopharmaceutical quality assurance;
   f. Radiological health and safety;
   g. Drug storage and disposition; and
   h. Education of professional staff, support staff, and patients;
10. Recordkeeping;
11. Sanitation;
12. Security;
13. Drug delivery requirements for:
   a. Transportation,
   b. Security,
   c. Radiological health and safety procedures,
   d. Temperature and other environmental controls, and
   e. Emergency provisions; and
14. Patient education.

Historical note
Adopted effective July 8, 1997 (Supp. 97-3).

R4-23-683. Reserved

R4-23-684. Reserved

R4-23-685. Reserved

R4-23-686. Reserved

R4-23-687. Reserved

R4-23-688. Reserved

R4-23-689. Reserved

R4-23-690. Reserved

R4-23-691. Repealed

Historical Note
Adopted effective Dec. 3, 1974 (Supp. 75-1). Amended effective Aug. 12, 1988 (Supp. 88-3). Amended effective November 1, 1993 (Supp. 93-4). Repealed effective July 8, 1997 (Supp. 97-3).

R4-23-692. Compressed Medical Gas Distributor

A. Permit:
1. A person shall not manufacture, process, transfill, package, or label a compressed medical gas before a compressed medical gas distributor permit is issued by the Board or its designee following a satisfactory final inspection by a Board compliance officer.
2. Before operating as a compressed medical gas distributor, a person shall register with the FDA as a medical gas manufacturer and comply with the drug listing requirements of the federal act.
3. To obtain a compressed medical gas distributor permit a person shall submit a completed application, on a form furnished by the Board, to the Board's office.
4. A compressed medical gas distributor permittee shall distribute a compressed medical gas only:
   a. Pursuant to a compressed medical gas order; and
   b. If the compressed medical gas is listed on the distributor's permit application. To receive approval to distribute an additional compressed medical gas, the permittee shall request that the permit application be amended.
      i. The permittee shall send a written request to amend the permit application to the Board office.
      ii. The request shall include documentation that the FDA has approved manufacture of the additional compressed medical gas not listed on the original permit application.
      iii. If a request to amend an original permit application includes the documentation referenced in subsection (A)(4)(b)(ii) and if the Board or its designee determines that the amendment is in the interest of public health and safety, the Board or its designee shall approve the request to amend within 30 days of receipt.
5. A compressed medical gas distributor permit is subject to denial, suspension, or revocation under A.R.S. § 32-1932.

B. Current Good Manufacturing Practice: A compressed medical gas distributor permittee shall comply with the current good manufacturing practice requirements of 21 CFR 210 through 211, published April 1, 1996, (and no future amendments or editions), incorporated by reference and on file with the Board and the office of the Secretary of State.

C. Records: A compressed medical gas distributor permittee shall establish and implement written procedures for maintaining records pertaining to production, transfilling, process control, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law.
1. A permittee shall retain the records required by this Article and 21 CFR 210 through 211 for at least two years

after distribution of the compressed medical gas or one year after the expiration date of the compressed medical gas, whichever is longer.

2. A permittee shall make the records required by this Article and 21 CFR 210 through 211 available within 48 hours for review by the Board, its compliance officers, or the FDA.

D. Inspections: A permittee shall make the compressed medical gas distributor's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.

Historical Note

Adopted effective January 12, 1998 (Supp. 98-1).

R4-23-693. Compressed Medical Gas Supplier

A. Permit:

1. A person shall not supply a compressed medical gas before a compressed medical gas supplier permit is issued by the Board or its designee following a satisfactory final inspection by a Board compliance officer.
2. To obtain a compressed medical gas supplier permit a person shall submit a completed application, on a form furnished by the Board, to the Board's office.
3. A compressed medical gas supplier permittee shall supply a compressed medical gas only:
   a. Pursuant to a compressed medical gas order, and
   b. To the consumer, patient, or agent of the consumer or patient for whom the compressed medical gas order is written.
4. A compressed medical gas supplier permittee shall not manufacture, process, transfill, package, or label a compressed medical gas, except as set forth in subsection (B)(2).

B. Records: A compressed medical gas supplier permittee shall establish and implement written procedures for maintaining records pertaining to acquisition and distribution of, and complaints related to, compressed medical gases.

1. A permittee shall ensure that a compressed medical gas order is obtained and filed for each compressed medical gas container supplied by the permittee.
2. A permittee shall ensure that each compressed medical gas container supplied by the permittee contains a label bearing the name and address of the compressed medical gas supplier.
3. A permittee shall retain the records required by this Article for at least two years after supplying the compressed medical gas or one year after the expiration date of the compressed medical gas, whichever is longer.
4. A permittee shall make the records required by this Article available within 48 hours for review by the Board or its compliance officers.

C. Inspections: A permittee shall make the compressed medical gas supplier's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.

Historical Note

Adopted effective January 12, 1998 (Supp. 98-1).

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS – GENERAL PROVISIONS

R4-23-701. Long-term Care Facilities Pharmacy Services: Consultant Pharmacist

A. The long-term care consultant pharmacist as defined in R4-23-110, in cooperation with the pharmacist-in-charge of a provider pharmacy shall:

1. Prepare, implement, review, and revise written policies and procedures for the safe and efficient receipt, distribution, and storage of pharmaceutical products by the long-term care facility in the manner specified in R4-23-671(E);
2. Make the policies and procedures available in the provider pharmacy and long-term care facility for employee reference and inspection by the Board or its designee; and
3. Ensure that the written policies and procedures required under (A)(1) include the following:
   a. Specification for the storage, distribution, and procurement of drugs and biologicals;
   b. Resident evaluation programs that relate to monitoring the therapeutic response and use of all drugs and biologicals prescribed or administered to residents, using as guidelines the most current indicators established by the Centers for Medicare and Medicaid Services, United States Department of Health and Human Services as required in 42 CFR 483.60, published October 1, 2001, and no future amendments or editions, incorporated by reference and on file with the Board and the Office of the Secretary of State;
   c. Pharmacist assistance in drug-related emergency situations on a 24-hour basis;
   d. Controlled substance accountability including:
      i. Date and time of administration,
      ii. Name of the person who administers the controlled substance,
      iii. Documenting and verifying of any wasted or partial doses, and
      iv. Exception reports for refused doses;
   e. Prescription order requirements;
   f. Approved abbreviations;
   g. Stop-order procedures;
   h. Pass and discharge prescription order procedures;
   i. Emergency drug supply unit procedures;
   j. Formulary procedures, including development, review, modification, use, and documentation, if applicable;
   k. Security and temperature control procedures for all drugs and biologicals;
   l. Disposal procedures that comply with subsection (D) for discontinued or outdated, prescription-only drugs or containers with illegible or missing labels; and
   m. Procedures for identifying and reporting to proper authorities drug irregularities and dispensing errors.

B. A long-term care consultant pharmacist shall ensure that:

1. A pharmacist evaluates and verifies a prescription order of a long-term care facility resident in compliance with R4-23-402(A)(5) and (6);
2. The prescription order of a long-term care facility resident contains:
   a. Resident's name;
   b. Facility name or address;
   c. Drug name, strength, and dosage form;
   d. Directions for use;
   e. Date issued; and
   f. Name of prescriber;
3. When a provider pharmacy is not open for business, arrangements are made in advance by the long-term care consultant pharmacist, in cooperation with the pharmacist-in-charge of the provider pharmacy and the director of nursing and medical staff of the long-term care facility, for providing emergency drugs for the licensed nursing staff to administer to the residents of the facility using an emergency drug supply unit located at the facility;

4. The label and packaging of prescription-only and nonprescription drugs intended for use within a long-term care facility complies with R4-23-701.01 and state and federal law; and
5. A long-term care facility's personnel is informed that laws governing controlled substances require that a long-term care facility:
   a. Store controlled substances listed in A.R.S. § 36-2513 in a separately locked and permanently affixed compartment, unless the facility uses a single-unit package medication distribution system, and
   b. Maintain accurate records of controlled substance administration or ultimate disposition.

C. The long-term care consultant pharmacist shall ensure availability of records and reports designed to provide the data necessary to evaluate the drug use of each long-term care facility resident that include the following:
1. Provider pharmacy patient profiles and long-term care facility medication administration records;
2. Reports of suspected adverse drug reactions;
3. Inspection reports of drug storage areas with emphasis on detecting outdated drugs; and
4. Accountability reports, including all drug destruction forms.

D. A long-term care consultant pharmacist or pharmacist-in-charge of a provider pharmacy shall ensure that:
1. Discontinued or outdated drugs, including controlled substances, are destroyed or disposed of:
   a. Under the supervision of either a long-term care consultant pharmacist or a pharmacist employed by a provider pharmacy and witnessed by the long-term care facility administrator or the administrator's designee;
   b. List by drug name, strength, dosage form, and quantity; and
   c. In a timely manner using methods consistent with state and local requirements and subject to review by the Board or its designee; and
2. Drug containers with illegible or missing labels are:
   a. Identified; and
   b. Replaced or relabeled by a pharmacist employed by the pharmacy that dispensed the prescription medication.

Historical Note

Former Rules 6.8110, 6.8120, 6.8130, 6.8140, 6.8150, 6.8160, and 6.8170; Amended effective Aug. 10, 1978 (Supp. 78-4). Section repealed, new Section adopted effective December 18, 1992 (Supp. 92-4). Amended by final rulemaking at 9 A.A.R. 1064, effective May 4, 2003 (Supp. 03-1).

R4-23-701.01. Long-term Care Facilities Pharmacy Services: Provider Pharmacy

The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that:
1. A prescription medication is provided only by a valid prescription order for an individual long-term care facility resident, properly labeled for that resident, as specified in this subsection. Nothing in this Section shall prevent a provider pharmacy from supplying nonprescription drugs in a manufacturer's unopened container or emergency drugs using an emergency drug supply unit as specified in R4-23-701.02;
2. A prescription medication label for a long-term care facility resident complies with A.R.S. §§ 32-1963.01(C) and (I), 32-1968, and 36-2525 and the applicable parts of R4-23-658(D), and contains:
   a. The drug name, strength, dosage form, and quantity; and
   b. The beyond-use-date;
3. Only a pharmacist employed by the pharmacy that dispensed the prescription medication may, through the exercise of professional judgement, relabel or alter a prescription medication label that is illegible or missing;
4. The long-term care facility develops and implements drug recall policies and procedures that protect the health and safety of facility residents. The drug recall procedures shall include immediate discontinuation of any recalled drug and notification of the prescriber and director of nursing of the facility; and
5. The provider pharmacy or any of its employees does not pay any rebate under A.R.S. § 32-1932(D) and R4-23-404.

Historical Note

Adopted effective December 18, 1992 (Supp. 92-4). Amended by final rulemaking at 9 A.A.R. 1064, effective May 4, 2003 (Supp. 03-1).

R4-23-701.02. Long-term Care Facilities Pharmacy Services: Emergency Drugs

A. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that an emergency drug supply unit is available within the long-term care facility.

B. An emergency drug supply unit shall contain only a drug that meets the following criteria:
1. The drug is necessary to meet the emergent and immediate needs of long-term care facility residents as determined by the provider pharmacy's pharmacist-in-charge in consultation with the long-term care facility's medical director and nursing director; and
2. The drug is packaged and labeled to include the drug name, strength, dosage form, manufacturer, lot number, and expiration date and provider pharmacy's name, address, telephone number, and pharmacist's initials.

C. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that an emergency drug supply unit:
1. Is stored in an area that:
   a. Is temperature controlled; and
   b. Prevents unauthorized access;
2. Contains on the exterior of the emergency drug supply unit a label to indicate that the contents are for emergency use only;
3. Contains on the exterior of the emergency drug supply unit a complete list of the contents of the unit by drug name, strength, dosage form, expiration date, and quantity and the provider pharmacy's name, address, and telephone number; and
4. Contains on the exterior of the emergency drug supply unit a label that indicates the date of and person responsible for the last inspection of the emergency drug supply unit.

D. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:
1. Prepare and implement written policies and procedures for the storage and use of an emergency drug supply unit in a long-term care facility in the manner specified in R4-23-671(E),
2. Make the policies and procedures available in the provider pharmacy and long-term care facility for employee reference and inspection by the Board or its designee, and

3. Ensure that the written policies and procedures include the following:
   a. Drug removal procedures that requires:
      i. The long-term care facility's personnel receive a valid prescription order for each drug removed from the emergency drug supply unit,
      ii. The long-term care facility's personnel notify the provider pharmacy when a drug is removed from the emergency drug supply unit, and
      iii. The provider pharmacy's personnel restock the emergency drug supply unit within 48 hours of receiving the notification required in subsection (D)(3)(a)(ii),
   b. Outdated drug replacement procedures that requires:
      i. The provider pharmacy's personnel check for outdated drugs in the emergency drug supply unit once a month,
      ii. The long-term care facility's personnel notify the provider pharmacy when an outdated drug is found in the emergency drug supply unit,
      iii. The provider pharmacy's personnel remove an outdated drug from the emergency drug supply unit within 48 hours of receiving the notification required in subsection (D)(3)(b)(ii), and
      iv. The provider pharmacy's personnel restock the emergency drug supply unit within 48 hours of receiving the notification required in subsection (D)(3)(b)(ii)
   c. Security and inspection procedures, and
4. Educate pharmacy and long-term care facility personnel in the storage and use of an emergency drug supply unit.

Historical Note
Adopted effective December 18, 1992 (Supp. 92-4). Amended by final rulemaking at 9 A.A.R. 1064, effective May 4, 2003 (Supp. 03-1).

R4-23-701.03. Long-term Care Facilities Pharmacy Services: Emergency Drug Prescription Order
The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that every emergency drug prescription order is evaluated according to the requirements of R4-23-402(A) by a pharmacist within 72 hours of the first dose of drug administered by long-term care facility personnel under the emergency drug prescription order.

Historical Note
Adopted effective December 18, 1992 (Supp. 92-4). Amended by final rulemaking at 9 A.A.R. 1064, effective May 4, 2003 (Supp. 03-1).

R4-23-702. Repealed

Historical Note
Former Rules 6.8210, 6.8211, 6.8212, 6.8213, 6.8214, 6.8221, 6.8222, 6.8223, 6.8824, 6.8231, 6.8232, 6.8233, 6.8241, 6.8242, and 6.8243; Amended effective August 10, 1978 (Supp. 78-4). Repealed effective December 18, 1992 (Supp. 92-4).

R4-23-703. Assisted Living Facilities
A. Assisted living facilities are licensed by the state Department of Health Services.
B. A pharmacy shall:
1. Only dispense, sell, or deliver a prescription or nonprescription drug to an assisted living facility resident after receiving a prescription order for the drug from the resident's medical practitioner;
2. Label, in accordance with A.R.S. §§ 32-1963.01 and 32-1968, all drugs dispensed, sold, or delivered to an assisted living facility resident;
3. Obtain a copy of the current Arizona Department of Health Services license issued to an assisted living facility before dispensing drugs to that facility's resident; and
4. Maintain, for inspection by a Board compliance officer, a file containing the license copy required in subsection (B)(3).

C. In addition to the labeling requirements of A.R.S. §§ 32-1963.01 and 32-1968, the label on a prescription medication for an assisted living facility resident shall include the name, strength, and quantity of the drug and a beyond-use date.
D. If the label on an assisted living facility resident's drug container becomes damaged or soiled, a pharmacist employed by the pharmacy that dispensed the drug container, through the exercise of professional judgment, may relabel the drug container. Only a pharmacist is permitted to label a drug container or alter the label of a drug container.
E. A pharmacist may help assisted living facility personnel to develop written policies and procedures for the procurement, administration, storage, control, recordkeeping, and disposal of drugs in the facility and provide other information concerning drugs that assisted living facilities should have for safe and effective supervision of drug self-administration.
F. A pharmacist shall not pay any rebate to an assisted living facility according to R4-23-404 and A.R.S. § 32-1932(B)(1).

Historical Note
Former Rules 6.8310, 6.8320, 6.8330, 6.8340, 6.8350, 6.8360, and 6.8370; Amended effective August 10, 1978 (Supp. 78-4). Amended by final rulemaking at 5 A.A.R. 2561, effective July 16, 1999 (Supp. 99-3).

R4-23-704. Repealed

Historical Note
Former Rules 6.8410, 6.8411, 6.8412, 6.8413, 6.8414, 6.8415, 6.8416, and 6.8417. Section R4-23-704 repealed by final rulemaking at 5 A.A.R. 862, effective March 3, 1999 (Supp. 99-1).

R4-23-705. Repealed

Historical Note
Former Rules 6.8420, 6.8421, 6.8422, 6.8423, 6.8424, 6.8425, 6.8426, 6.8427, 6.8428, and 6.8429. Amended effective August 10, 1978 (Supp. 78-4). Amended effective August 24, 1992 (Supp. 92-3). Repealed effective December 18, 1992 (Supp. 92-4).

R4-23-706. Repealed

Historical Note
Former Rules 6.8431, 6.8432, 6.8433, 6.8434, 6.8435, 6.8436, and 6.8437; Amended effective August 10, 1978 (Supp. 78-4). Amended subsections (C), (E), (F), and (G) effective April 20, 1982 (Supp. 82-2). Section R4-23-706 repealed by final rulemaking at 5 A.A.R. 862, effective March 3, 1999 (Supp. 99-1).

R4-23-707. Repealed

Historical Note
Former Rules 6.8441, 6.8442, 6.8450, 6.8451, 6.8452, 6.8453, 6.8454, 6.8455, 6.8456, and 6.8457. Section R4-23-707 repealed by final rulemaking at 5 A.A.R. 862, effective March 3, 1999 (Supp. 99-1).

R4-23-708. Repealed

Historical Note
Former Rules 6.8461, 6.8462, 6.8463, and 6.8464. Section R4-23-708 repealed by final rulemaking at 5 A.A.R. 862, effective March 3, 1999 (Supp. 99-1).

R4-23-709. Repealed

Historical Note
Former Rules 6.8471, 6.8472, and 6.8473. Section R4-23-709 repealed by final rulemaking at 5 A.A.R. 862, effective March 3, 1999 (Supp. 99-1).

ARTICLE 8. DRUG CLASSIFICATION

Article 8, consisting of Sections R4-23-801 and R4-23-802, recodified from Article 5 at 9 A.A.R. 4011, effective August 18, 2003 (Supp. 03-3).

R4-23-801. Dietary Supplements
A person who sells, distributes, or provides a product that is labeled as a dietary supplement and is labeled or marketed as a treatment for any deficiency disease, for the correction of any symptom of disease, or for the prevention, mitigation, or cure of any disease, either by direct statement or by inference, is selling, distributing, or providing a drug and is subject to the requirements of A.R.S. Title 32, Chapter 18 and 4 A.A.C. 23.

Historical Note
Former Rules 7.1110, 7.1120, and 7.1130. Repealed effective November 4, 1998 (Supp. 98-4). Recodified from R4-23-501 at 9 A.A.R. 4011, effective August 18, 2003 (Supp. 03-3).

R4-23-802. Veterinary
Veterinary preparation: A veterinary drug manufacturer or supplier may distribute:

1. A prescription-only veterinary drug to:
   a. A veterinary medical practitioner licensed under A.R.S. Title 32, Chapter 21,
   b. A full-service drug wholesaler permitted under A.R.S. Title 32, Chapter 18, or
   c. A pharmacy permitted under A.R.S. Title 32, Chapter 18, and
2. A nonprescription veterinary drug to:
   a. A veterinary medical practitioner licensed under A.R.S. Title 32, Chapter 21,
   b. A nonprescription drug retailer permitted under A.R.S. Title 32, Chapter 18,
   c. A full-service or nonprescription drug wholesaler permitted under A.R.S. Title 32, Chapter 18, or
   d. A pharmacy permitted under A.R.S. Title 32, Chapter 18.

Historical Note
Former Rules 7.1210, 7.1220, and 7.1230. Repealed effective November 4, 1998 (Supp. 98-4). Recodified from R4-23-502 at 9 A.A.R. 4011, effective August 18, 2003 (Supp. 03-3).

R4-23-803. Repealed

Historical Note
Former Rules 7.1300, 7.1400, 7.1500, and 7.1000. Repealed effective November 4, 1998 (Supp. 98-4).

R4-23-804. Repealed

Historical Note
Former Rules 7.2100, 7.2200, 7.2300, 7.2410, 7.2420, and 7.2430. Repealed effective November 4, 1998 (Supp. 98-4).

ARTICLE 9. PENALTIES AND MISCELLANEOUS

R4-23-901. Penalty for Violations
Any person, firm, or corporation violating any provision of 4 A.A.C. 23 is subject to the penalties in A.R.S. § 32-1996. In addition, a license or permit issued under the provisions of A.R.S. Title 32, Chapter 18 is subject to suspension or revocation for violation of 4 A.A.C. 23.

Historical Note
Former Rule 9.0000. Amended by final rulemaking at 6 A.A.R. 3177, effective August 3, 2000 (Supp. 00-3).

ARTICLE 10. UNIFORM CONTROLLED SUBSTANCES AND DRUG OFFENSES

R4-23-1001. Repealed

Historical Note
Adopted effective August 2, 1982 (Supp. 82-4). Section repealed by final rulemaking at 6 A.A.R. 3177, effective August 3, 2000 (Supp. 00-3).

R4-23-1002. Repealed

Historical Note
Adopted effective August 2, 1982 (Supp. 82-4). Repealed effective November 4, 1998 (Supp. 98-4).

R4-23-1003. Records and Order Forms

A. Records

1. If the pharmacist-in-charge of a pharmacy is replaced by another pharmacist-in-charge, the new pharmacist-in-charge shall complete an inventory of all controlled substances in the pharmacy within 10 days of assuming the responsibility. This inventory and any other required controlled substance inventory shall:
   a. Include an exact count of all CII controlled substances;
   b. Include an exact count of all CIII through CV controlled substances or an estimated count if the stock container contains fewer than 1001 units;
   c. Indicate the date the inventory is taken and whether the inventory is taken before opening of business or after close of business for the pharmacy;
   d. Be signed by:
      i. The pharmacist-in-charge; or
      ii. For other required inventories, the pharmacist who does the inventory;
   e. Be kept separately from all other records; and
   f. Be available in the pharmacy for inspection by the Board or its designee for not less than three years.
2. A loss of a controlled substances shall be reported:
   a. Within 10 days of discovery,
   b. On a DEA form 106,
   c. By the pharmacist-in-charge of a pharmacy or manufacturer,
   d. By the permittee or manager of a full-service wholesaler, and
   e. To the federal Drug Enforcement Administration (DEA), the Narcotic Division of the Department of Public Safety (DPS), and the Board of Pharmacy. A copy of the DEA form 106 shall be kept on file by the pharmacy permittee. The DEA form 106 shall state whether the police investigated the loss.
3. Every person manufacturing any controlled substance, including repackaging or relabeling, shall record and retain the manufacturing, repackaging, or relabeling date for each controlled substance.

4. Every person receiving, selling, delivering, or disposing of any controlled substance shall record and retain for not less than three years the following information:
   a. The name, strength, dosage form, and quantity of each controlled substance received, sold, delivered, or disposed;
   b. The name, address, and DEA registration number of the person from whom each controlled substance is received;
   c. The name, address, and DEA registration number of the person to whom each controlled substance is sold or delivered or who disposes of each controlled substance; and
   d. The date of each transaction.

B. Order form. For purposes of A.R.S. § 36-2524, "Order Form" means DEA Form 222c.

Historical Note

Adopted effective August 2, 1982 (Supp. 82-4). Amended effective November 1, 1993 (Supp. 93-4). Amended effective April 1, 1995; filed January 31, 1995 (Supp. 95-1). Amended by final rulemaking at 6 A.A.R. 3177, effective August 3, 2000 (Supp. 00-3).

R4-23-1004. Repealed

Historical Note

Adopted effective August 2, 1982 (Supp. 82-4). Repealed effective November 4, 1998 (Supp. 98-4).

R4-23-1005. Substances Excepted from the Schedules of Controlled Substances

A. All over-the-counter non-narcotic substances containing limited amounts of controlled substances that are excluded from all controlled substance schedules by 21 CFR § 1308.22 April 1, 1999, and no future editions or amendments, incorporated by reference and on file with the Board and the Office of the Secretary of State, are excluded from all controlled substance schedules in Arizona.

B. All chemical preparations or mixtures containing one or more controlled substances listed in any schedule that are exempted from all controlled substance schedules by 21 CFR § 1308.24 April 1, 1999, and no future editions or amendments, incorporated by reference and on file with the Board and the Office of the Secretary of State, are exempted from all controlled substance schedules in Arizona.

C. All prescription-only drugs that are exempted by 21 CFR § 1308.32 April 1, 1999, and no future editions or amendments, incorporated by reference and on file with the Board and the Office of the Secretary of State, are exempted from all controlled substance schedules in Arizona.

Historical Note

Adopted effective August 2, 1982 (Supp. 82-4). Amended by final rulemaking at 6 A.A.R. 3177, effective August 3, 2000 (Supp. 00-3).

R4-23-1006. Substances Excepted from Drug Offenses

The following materials, compounds, mixtures, or preparations containing any stimulant or depressant substance included in A.R.S. §§ 13-3401(6)(b) or 13-3401(6)(c) are excepted from the definition of dangerous drugs under the authority of A.R.S. § 32-1904(B)(14):

1. Over-the-counter drugs excepted in R4-23-1005(A).
2. Chemical preparations excepted in R4-23-1005(B).
3. Prescription-only drugs excepted in R4-23-1005(C).

Historical Note

Adopted effective August 2, 1982 (Supp. 82-4). Amended by final rulemaking at 6 A.A.R. 3177, effective August 3, 2000 (Supp. 00-3).

ARTICLE 11. PHARMACY TECHNICIANS

Article 11, consisting of R4-23-1101 through R4-23-1105, made by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-1101. Licensure and Eligibility

A. License required. A person shall not work as a pharmacy technician or pharmacy technician trainee in Arizona, unless the person:
1. Possesses a pharmacy technician or pharmacy technician trainee license issued by the Board;
2. Reads and discusses with the pharmacist-in-charge of the pharmacy where employed, the Board rules concerning pharmacy technicians and pharmacy technician trainees, the pharmacy technician and pharmacy technician trainee job description, and the policies and procedures manual of that pharmacy; and
3. Dates and signs a statement that the person has complied with subsection (A)(2).

B. Eligibility.
1. To be eligible for licensure as a pharmacy technician trainee, a person shall:
   a. Be of good moral character,
   b. Be at least 18 years of age, and
   c. Have a high school diploma or the equivalent of a high school diploma.
2. To be eligible for licensure as a pharmacy technician, a person shall:
   a. Meet the requirements of subsection (B)(1),
   b. Complete a pharmacy technician training program that meets the standards prescribed in R4-23-1105, and
   c. Pass the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination.

C. A pharmacy technician delinquent license. Before an Arizona pharmacy technician license will be reinstated, a pharmacy technician whose Arizona pharmacy technician license is delinquent for five or more consecutive years shall furnish to the Board satisfactory proof of fitness to be licensed as a pharmacy technician and pay all past due biennial renewal fees and penalty fees. Satisfactory proof includes:
1. For a person with a delinquent license who is practicing as a pharmacy technician out-of-state with a pharmacy technician license issued by another jurisdiction:
   a. Proof of current, unrestricted pharmacy technician licensure in another jurisdiction; and
   b. Proof of employment as a pharmacy technician during the last 12 months; or
2. For a person with a delinquent license who did not practice as a pharmacy technician within the last 12 months:
   a. Take and pass a Board-approved pharmacy technician examination, and
   b. Complete 120 hours of pharmacy technician training as a pharmacy technician trainee licensed under R4-23-1103, or
   c. Complete 480 hours of pharmacy technician training as a pharmacy technician trainee licensed under R4-23-1103.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-1102. Pharmacy Technician Licensure

A. Application. An applicant for licensure as a pharmacy technician shall:
1. Provide the Board proof that the applicant is eligible under R4-23-1101(B)(2), including documentation that the applicant:
   a. Completed a pharmacy technician training program that meets the standards prescribed in R4-23-1105; and
   b. Passed the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination;
2. File an application on a form furnished by the Board, that includes:
   a. Applicant's name, address, mailing address, if different, telephone number, and social security number;
   b. Whether the applicant has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charge, and if so, indicate charge, charge date, conviction date, and jurisdiction;
   c. Whether the applicant has ever had a pharmacy technician license revoked, suspended, or has a pending revocation or suspension action, or denied in this state or any other jurisdiction, and if so, indicate where and when;
   d. Pharmacy name and address where the pharmacy technician will practice;
   e. Date signed and applicant's verified signature; and
   f. The wall license and initial licensure fees specified in R4-23-205.

B. Licensure. Within seven business days of receipt of a completed application, fees, and other information specified in subsection (A), the Board office shall determine whether the application is complete. If the application is complete, the Board shall assess whether the applicant is qualified under statute and rule. If the applicant is qualified, the Board office shall issue a license number and mail a license to the applicant. An applicant who is issued a license number may begin practice as a pharmacy technician. The Board office shall mail a wall license to the licensee within 14 days of issuing the license number.

C. License renewal. To renew a license, a pharmacy technician shall submit a license renewal form supplied by the Board with the biennial renewal fee specified in R4-23-205. The Board office will process the application for renewal in the same manner described in subsection (B).

D. If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925, the pharmacy technician license is suspended and the licensee shall pay a penalty as provided in A.R.S. § 32-1925 and R4-23-205 to vacate the suspension.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-1103. Pharmacy Technician Trainee Licensure

A. Application. An applicant for licensure as a pharmacy technician trainee shall:
1. Provide the Board proof that the applicant is eligible under R4-23-1101(B)(1); and
2. File an application on a form furnished by the Board, that includes:
   a. Applicant's name, address, mailing address, if different, telephone number, and social security number;
   b. Whether the applicant has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charge, and if so, indicate charge, charge date, conviction date, and jurisdiction;
   c. Whether the applicant has ever had a pharmacy technician or pharmacy technician trainee license revoked, suspended, or has a pending revocation or suspension action, or denied in this state or any other jurisdiction, and if so, indicate where and when;
   d. Pharmacy name and address where the pharmacy technician trainee will complete the pharmacy technician training program;
   e. Date signed and applicant's verified signature; and
   f. The wall license and initial licensure fees specified in R4-23-205.

B. Licensure.
1. Within seven business days of receipt of a completed application, fees, and other information specified in subsection (A), the Board office shall determine whether the application is complete. If the application is complete, the Board shall assess whether the applicant is qualified under statute and rule. If the applicant is qualified, the Board office shall issue a license number and mail a license to the applicant. An applicant who is issued a license number may begin practice as a pharmacy technician trainee. The Board office shall mail a wall license to the licensee within 14 days of issuing the license number. A pharmacy technician trainee license is valid for 24 months from the date issued.
2. A pharmacy technician trainee who does not complete the prescribed training program and pass the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination before the pharmacy technician trainee's license expires is not eligible for licensure as a pharmacy technician and shall not practice as a pharmacy technician or pharmacy technician trainee.

C. The Board may allow a pharmacy technician trainee whose license expires before the pharmacy technician trainee completes the prescribed training program and passes the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination to reapply for licensure not more than one time. A pharmacy technician trainee whose license has expired may make a special request to the Board under R4-23-401 for approval to reapply for licensure.

D. The Board shall base its decision to grant or deny a special request to reapply for licensure on an assessment of:
1. The reasons the pharmacy technician trainee did not complete a pharmacy technician training program and the likelihood that the pharmacy technician trainee will complete a pharmacy technician training program within the next 24 months,
2. The reasons the pharmacy technician trainee failed the pharmacy technician examination and the likelihood that the pharmacy technician trainee will pass the pharmacy technician examination within the next 24 months, and
3. Other extenuating circumstances.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-1104. Pharmacy Technicians and Pharmacy Technician Trainees

A. Permissible activities of a pharmacy technician trainee. Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a pharmacy technician trainee may assist a graduate intern, pharmacy intern, or pharmacist with the following when applicable to the pharmacy practice site:
1. Record on the original prescription order the prescription serial number and date dispensed;
2. Initiate or accept verbal or electronic refill authorization from a medical practitioner or medical practitioner's agent and record, on the original prescription order or by an alternative method approved by the Board or its designee, the medical practitioner's name, patient name, name and quantity of prescription medication, specific refill information, and name of medical practitioner's agent, if any;
3. Record information in the refill record or patient profile;
4. Type and affix a label for a prescription medication or enter information for a new or refill prescription medication into a computer, if a pharmacist verifies the accuracy and initials in handwriting or by another method approved by the Board or its designee the finished label prepared by the technician before the prescription medication is dispensed to the patient;
5. Reconstitute a prescription medication, if a pharmacist checks the ingredients and procedure before reconstitution and verifies the final product after reconstitution;
6. Retrieve, count, or pour a prescription medication, if a pharmacist verifies the contents of the prescription medication against the original prescription medication container or by an alternative drug identification method approved by the Board or its designee;
7. Prepackage drugs in accordance with R4-23-402(A); and
8. Measure, count, pour, or otherwise prepare and package a drug needed for hospital inpatient dispensing, if a pharmacist verifies the accuracy, measuring, counting, pouring, preparing, packaging, and safety of the drug before the drug is delivered to a patient care area.

B. Permissible activities of a pharmacy technician. Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a pharmacy technician may:
1. Perform the activities listed in subsection (A); and
2. After completing a drug compounding training program developed by the pharmacy permittee or pharmacist-in-charge under R4-23-1105, assist a pharmacist, graduate intern, or pharmacy intern in compounding prescription medications and sterile or non-sterile pharmaceuticals in accordance with written policies and procedures, if the preparation, accuracy, and safety of the final product is verified by a pharmacist before dispensing.

C. Prohibited activities. A pharmacy technician or pharmacy technician trainee shall not perform a function reserved for a pharmacist, graduate intern, or pharmacy intern in accordance with R4-23-402 or R4-23-653.

D. A pharmacy technician or pharmacy technician trainee shall wear a badge indicating name and title while on duty.

E. Before employing a pharmacy technician or pharmacy technician trainee, a pharmacy permittee or pharmacist-in-charge shall develop and implement policies and procedures in the same manner described in R4-23-653(A) for pharmacy technician and pharmacy technician trainee activities as specified in subsection (F).

F. The policies and procedures shall include the following:
1. For all practice sites:
   a. Supervisory controls and verification procedures to ensure the quality and safety of pharmaceutical service;
   b. Employment performance expectations for a pharmacy technician and pharmacy technician trainee;
   c. The activities a pharmacy technician or pharmacy technician trainee may perform as specified in R4-23-1104(A) and (B);
   d. Pharmacist and patient communication;
   e. Reporting, correcting, and avoiding medication and dispensing errors;
   f. Security procedures for:
      i. Confidentiality of patient prescription records, and
      ii. The pharmacy area;
   g. Automated medication distribution system;
   h. Compounding procedures for pharmacy technicians; and
   i. Brief overview of state and federal pharmacy statutes and rules;
2. For community and limited-service pharmacy practice sites:
   a. Prescription dispensing procedures for:
      i. Accepting a new written prescription,
      ii. Accepting a refill request,
      iii. Selecting a drug product,
      iv. Counting and pouring,
      v. Labeling, and
      vi. Obtaining refill authorization;
   b. Computer data entry procedures for:
      i. New and refill prescriptions,
      ii. Patient's drug allergies,
      iii. Drug-drug interactions,
      iv. Drug-food interactions,
      v. Drug-disease state contraindications,
      vi. Refill frequency,
      vii. Patient's disease and medical condition,
      viii. Patient's age or date of birth and gender, and
      ix. Patient profile maintenance; and
3. For hospital pharmacy practice sites:
   a. Medication order procurement and data entry,
   b. Drug preparation and packaging,
   c. Outpatient and inpatient drug delivery, and
   d. Inspection of drug storage and preparation areas and patient care areas.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).

R4-23-1105. Pharmacy Technician Training Program

A. Nothing in this Section prevents additional offsite training of a pharmacy technician.

B. Pharmacy technician training program.
1. A pharmacy permittee or pharmacist-in-charge shall develop and implement in the same manner described in R4-23-653(A) a pharmacy technician training program based on the needs of the individual pharmacy;
2. A pharmacy permittee or pharmacist-in-charge shall ensure that the pharmacy technician training program includes training guidelines that:
   a. Define the specific tasks a pharmacy technician trainee is expected to perform,
   b. Specify how and when the pharmacist-in-charge will access the pharmacy technician trainee's competency, and

c. Address the policies and procedures specified in R4-23-1104(F) and the permissible activities specified in R4-23-1104(A) and (B);

3. A pharmacist-in-charge shall:
   a. Document a pharmacy technician trainee's progress throughout the training program,
   b. Date and sign a statement attesting that a pharmacy technician trainee has successfully completed the training program,
   c. Maintain the documentation required in this subsection and R4-23-1101(A)(3) for inspection by the Board or its designee, and
   d. Provide to the pharmacy technician trainee a copy of the statement required in subsection (B)(3)(b).

C. Drug compounding training program.

1. A pharmacy permittee or pharmacist-in-charge shall develop and implement in the same manner described in R4-23-653(A) a drug compounding training program based on the needs of the individual pharmacy;
2. A pharmacy permittee or pharmacist-in-charge shall ensure that the drug compounding training program includes training guidelines that:
   a. Define the specific tasks a pharmacy technician is expected to perform,
   b. Specify how and when the pharmacist-in-charge will access the pharmacy technician's competency, and
   c. Address the following procedures and tasks:
      i. Area preparation,
      ii. Component preparation,
      iii. Aseptic technique and product preparation,
      iv. Packaging and labeling, and
      v. Area clean up;
3. A pharmacist-in-charge shall:
   a. Document a pharmacy technician's progress throughout the training program, and
   b. Date and sign a statement attesting that a pharmacy technician trainee has successfully completed the training program,
   c. Maintain the documentation required in this subsection for inspection by the Board or its designee.

D. A pharmacy technician shall perform only those tasks, listed in R4-23-1104(B), for which training and competency has been demonstrated.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 1192, effective May 1, 2004 (Supp. 04-1).